

S. HRG. 113-799

**TEN YEARS LATER: A LOOK AT THE MEDICARE  
PRESCRIPTION DRUG PROGRAM**

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**HEARING**  
BEFORE THE  
**SPECIAL COMMITTEE ON AGING**  
**UNITED STATES SENATE**  
**ONE HUNDRED THIRTEENTH CONGRESS**

FIRST SESSION

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WASHINGTON, DC

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WEDNESDAY, MAY 22, 2013

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## **TEN YEARS LATER: A LOOK AT THE MEDICARE PRESCRIPTION DRUG PROGRAM**

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**WEDNESDAY, MAY 22, 2013**

U.S. SENATE,  
SPECIAL COMMITTEE ON AGING,  
*Washington, DC.*

The Committee met, pursuant to notice, at 2:33 p.m., in Room 366, Dirksen Senate Office Building, Hon. Bill Nelson, Chairman of the Committee, presiding.

Present: Senators Nelson, Wyden, Warren, Collins, and Ayotte.

### **OPENING STATEMENT OF SENATOR BILL NELSON, CHAIRMAN**

The CHAIRMAN. Good afternoon. In the interest of time, since a vote will be called at 3:40, Senator Collins and I are going to forego the opening statements, and so we will get right in with your testimony. We will insert our statements in the record.

[The prepared statement of Chairman Nelson follows:]

**Opening Statement of Chairman Bill Nelson  
U.S. Senate Special Committee on Aging  
Hearing: "10 Years Later: A Look at the Medicare Prescription Drug Program"  
May 22, 2013**

Good afternoon and thank you to all of you for being here today as we take a look at the Medicare prescription drug program.

Since Congress passed legislation creating the Medicare drug benefit ten years ago, the program has provided millions of seniors with access to affordable medications. As a result many no longer have to choose between buying food for the pantry or going without needed prescriptions.

And, not only is the program helping seniors afford their medications and stay healthy, the Congressional Budget office says it's also saving taxpayers' money.

That's why I believe that now, more than ever, we must work to make Medicare Part D as strong as it can be. But, while much success has been achieved, we still have some work to do.

For instance, I believe many drugs are just too expensive. That's why I've long supported the Medicare Drug Savings Act, which would reduce the amount Medicare pays drug companies for prescription medications of some nine-million, low-income seniors who also qualify for Medicaid. When the Medicare drug program went into effect in 2006, these so-called "dual eligible" beneficiaries had been receiving their medications through Medicaid but were instead shifted into the new Medicare drug program, resulting in the government paying far higher prices for drugs.

Allowing the federal government to negotiate a fair rebate on drugs provided through Medicare just makes common sense.

There are also many more ways I believe we can improve Medicare Part D.

When folks like Alberto Vega, a small business owner with Part D coverage from Miami, question why the government makes it so difficult, I know there are steps we can take to improve the day-to-day experience for many seniors.

For instance, let's ensure that there is a fair and functional appeals process to help seniors with the out-of-pocket costs they simply can't afford—particularly for high-cost specialty drugs.

I am shocked that for drugs on these so-called specialty tiers, beneficiaries do not even have the right to appeal for help at all.

We can work together to ensure that no senior ever has to leave the pharmacy without the drugs they need.

And, we can make certain that picking the right prescription drug plan is a transparent and streamlined process. Senator Collins and I have requested a GAO study in advance of open enrollment this fall to look into that issue.

We must ensure that the online information Medicare beneficiaries rely on when choosing a plan is accurate and reliable.

So, I look forward to working with the members of the committee on these and other issues related to the Medicare prescription drug program.

We have an excellent panel of witnesses today. I thank you all for being here, and look forward to hearing from each of you.

Sen. Collins...

[The prepared statement of Senator Collins follows:]



UNITED STATES SENATOR  
**SUSAN M. COLLINS**



PRESS RELEASE

For Immediate Release  
May 22, 2013

Contact: [Kevin Kelley](#) or [Jeremy Kirkpatrick](#)  
202-224-2523

**STATEMENT OF SENATOR SUSAN COLLINS**

**SENATE SPECIAL COMMITTEE ON AGING**

**“TEN YEARS LATER: A LOOK AT THE MEDICARE PRESCRIPTION DRUG PROGRAM”**

**MAY 22, 2013**

Mr. Chairman, thank you for calling this hearing to highlight how important good prescription drug coverage is to the overall health and well-being of our nation’s seniors. As we approach the ten-year anniversary of the Medicare Modernization Act, which created the Medicare prescription drug program, it is time to examine what is working well and what may need improvement.

Prescription drugs are as important to a Medicare beneficiary’s health today as a hospital bed was in 1965, when Medicare was created. Many patients find their drug regimen protects them from becoming sicker and reduces the need to treat serious illness through hospitalization and surgery.

In stark contrast to the vast majority of insurance policies for the under-65 population, until 2006, Medicare did not pay for most outpatient prescription drugs. I was a strong supporter of the Medicare Modernization Act of 2003, which brought Medicare into line with most private sector insurance plans and expanded the program to cover prescription drugs.

By any measure, the Medicare Part D program has been a tremendous success. It is an important life-saver for millions of Medicare beneficiaries and provides access to critical medications that previously were unaffordable and therefore unattainable.

Now, ninety percent of Medicare beneficiaries have affordable prescription drug coverage, and Part D program costs are dramatically lower – 45 percent – than initial projections. This may be the only entitlement program in history where actual experience has produced much lower costs – for both the government and for beneficiaries than was originally estimated.

To be sure, there was a learning curve and some confusion in the early days of the program. Today, however, nine out of ten seniors say that they are happy with their coverage. It is difficult to get nine out of ten people to agree on anything, and these high satisfaction rates are an endorsement of the program’s success.

There is also increasing evidence that the program is helping to lower seniors’ overall health care costs. A recent study in the *Journal of the American Medical Association* found that implementation of the Medicare

prescription drug program was followed by a \$1200 per year decrease in non-drug medical spending for beneficiaries who previously had limited drug coverage. Another study by Harvard researchers showed that the implementation of Medicare Part D significantly reduced the probability of hospitalization for eight conditions, leading to four percent fewer hospital admissions annually and significant savings.

The Medicare Part D program is extremely popular and is working very well; however, that does not mean that there is no room for improvement. I am concerned by some recent studies showing that many seniors do not choose the least expensive plan that meets their medication needs. These individuals may be overpaying for their coverage. Some seniors also say that they continue to find it difficult and confusing to pick the best plan for their needs.

These findings suggest that some beneficiaries may need more targeted assistance. In response to concerns that many seniors continue to overspend and remain confused by their Part D options, I have joined the Chairman in asking the GAO to examine the accuracy and transparency of plan information given to Medicare beneficiaries. We must make certain that this information is up-to-date, accurate and easy for consumers to use.

Again Mr. Chairman, I want to thank you for all of your work on these issues, and I look forward to the testimony of our witnesses.

The CHAIRMAN. Let me, first of all, introduce you all before.

We are going to hear from Margaret Woerner. Ms. Woerner—Dr. Woerner—is a Medicare beneficiary herself, and she has volunteered at the Medicare Rights Center in New York City for the past eight years. In this capacity, she has listened to other beneficiaries and their families, and provided them with information on a wide variety of issues. Being a volunteer and a beneficiary, Dr. Woerner has a unique perspective on Medicare Part D.

Jack Hoadley—Dr. Hoadley—is a research professor at the Health Policy Institute at Georgetown. Recently, Dr. Hoadley has studied various aspects of Medicare Part D, including the spending trends and the use of formularies. Dr. Hoadley was also recently appointed to a three-year term as a member of the Medicare Payment Advisory Commission.

And, Richard Smith, Executive Vice President for Policy and Research at the Pharmaceutical Research and Manufacturers Association—Mr. Smith has worked extensively in health care.

And, Robert Romasco, he is the President of AARP.

And so, this is a distinguished panel.

And because, Senator Wyden, I said we are going to forego the opening statements since we have a vote coming up, we will get right with the witnesses.

So, Dr. Woerner, we will start off with you.

Your full statement will be placed in the record, and if you all could give us about a five-minute summary, we would appreciate it. Thank you so much.

**STATEMENT OF MARGARET WOERNER, MEDICARE BENEFICIARY AND HELPLINE VOLUNTEER, MEDICARE RIGHTS CENTER**

Ms. WOERNER. My name is Margaret Woerner. I am a Medicare beneficiary and have been a helpline volunteer for the past eight years at the Medicare Rights Center in New York City.

The Medicare Rights Center is a national nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities.

As a volunteer, I provide information and counseling to Medicare Part D beneficiaries and their family members on a variety of issues. This work is deeply gratifying because I can help people solve very real life problems.

I have seen the positive impact that access to prescription drug coverage under the Part D benefit has had for so many older adults and people with disabilities. Yet, while these benefits are undeniable, many barriers to accessing needed medications still exist. I believe that the Part D benefit can be made even stronger by addressing these issues.

I speak to countless beneficiaries who go to the pharmacy to fill a prescription only to find that their Part D plan refuses to cover the medication. When this happens, most beneficiaries leave the pharmacy empty-handed and without answers.

Upon calling the plan, they are given any number of reasons for the denial. For example, the plan wants them to try a less expensive drug first, the drug is not on the plan's formulary, or the drug is being taken for an off-label indication.

Yet, before a beneficiary can even begin to appeal to have the drug covered, I must counsel that she first must request a written coverage determination from her plan and include a letter of support from her doctor. Many of the people I speak to have not received instructions from their plan on how to do this.

Callers often express frustration at the need to jump through so many hoops. Because of these hoops, some will try to pay for the prescriptions out of pocket; others will simply go without their medication because they cannot afford it.

I helped a 75-year-old woman living in Florida who received a denial notice from her Part D plan, stating that they would not authorize a drug for her rheumatoid arthritis without additional medical information. When she had previously been living in Ohio, this same plan covered the same drug. So she was quite confused and upset as to why they would not fill this prescription this time. She left the pharmacy without her medicine, and it took four weeks for her to get the prescription covered. In the meantime, she had to suffer through the pain and inflammation caused by her arthritis.

The large number of plans available and the frequent plan changes from year to year make it nearly impossible for many of our callers to make the right decision about enrolling in a new Part D plan or keeping their existing plan.

I have found that from year to year my own out-of-pocket costs for the same coverage and for the same medications can vary greatly from plan to plan.

I speak to many beneficiaries who attempt to understand their coverage before they enroll only to find out after they have enrolled that their medication is subject to numerous restrictions or that their costs are much higher than they can afford.

To get the most out of your coverage, you must know the differences between preferred brand name drugs versus nonpreferred brand name drugs versus preferred generic drugs versus nonpreferred generic drugs versus specialty drugs; you must know how to obtain your drugs from preferred in-network pharmacies versus nonpreferred in-network pharmacies versus mail-order pharmacies; and, of course, you must know whether your drugs are subject to any restrictions.

Part D has done many good things for older adults and people with disabilities, but there is much more that can be done to improve the program.

Thank you for the opportunity to testify about my experience helping people with Medicare Part D.

[The prepared statement of Ms. Woerner follows:]



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Testimony of Margaret Woerner  
Medicare Beneficiary and Medicare Rights Helpline Volunteer

Prepared for the  
United States Senate  
Special Committee on Aging

“10 Years Later: A Look at the Medicare Prescription Drug Program”

May 22, 2013

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Good afternoon, Mr. Chairman and Members of the Committee:

My name is Margaret Woerner. I am a Medicare beneficiary and have been a helpline volunteer for the past eight years at the Medicare Rights Center in New York City. The Medicare Rights Center is a national, non-profit organization that works to ensure access to affordable health care for older adults and people with disabilities. As a volunteer, I provide information and counseling to Medicare Part D beneficiaries and their families on a variety of issues. This work is deeply gratifying because I can help solve very real problems. I have seen the positive impact that access to prescription drug coverage under the Part D benefit has had for so many older adults and people with disabilities. Yet, while these benefits are undeniable, many barriers to accessing needed medications still exist. I believe that the Part D benefit can be made even stronger by addressing issues like improving the appeals process and simplifying Part D plans. Improvements like these can help many more access the care we earned.

On a regular basis, I speak to countless beneficiaries who go to the pharmacy to fill a prescription only to find that their Part D plan is refusing to cover the medication. When this happens, most beneficiaries leave the pharmacy empty-handed and without answers. Upon calling the plan, beneficiaries are given any number of reasons for the denial. For example, the plan wants them to try a less expensive alternative first; the drug is not on the plan's formulary; or the drug is being taken for an off-label indication. Other reasons for restricted access to the medication may include quantity limits or requirements for prior authorization. Yet, before a beneficiary can even begin to appeal to have the drug covered, I counsel that she must first

request a coverage determination from her plan and include a letter of support from her doctor. Many of the people I speak to have not received instructions from their plan on how to do this.

Callers often express frustration at the need to jump through so many hoops. Because of these hoops, some will try to pay for the prescriptions out-of-pocket, and others will simply go without their prescribed medication because they cannot afford it. I helped a 75 year-old woman living in Florida because she received a denial notice from her Part D plan stating that they would not authorize a drug for her rheumatoid arthritis unless they received additional medical information. When she had previously been living in Ohio, the same plan covered the same medication, so she was confused and upset as to why they would not fill the doctor's prescription this time. She left the pharmacy without her medicine and it took four weeks for her to fill the prescription. In the meantime, she had to muster through the pain and inflammation caused by her arthritis.

The large number of plans available and the frequent plan changes from year-to-year make it nearly impossible for many of our callers to make the right decision about enrolling in a new Part D plan or keeping their existing Part D plan. I have found that, depending on the year, my out-of-pocket costs for the same coverage and the same medications will vary greatly. I used to help my friends each year, but many no longer ask me for help because they are overwhelmed by the choices they must make. Not only do beneficiaries have to choose from *too* many plans, they have to weigh *too* many variables to make the best choice. Against my advice, many of my friends and my callers simply keep their old plan even if it is not in their own best interest.

I speak to many beneficiaries who attempt to understand their coverage prior to enrollment, only to find out after enrolling that their medication is subject to numerous restrictions or that their costs are much higher than they can afford. To get the most out of your coverage, you must know the differences between preferred brand name drugs vs. non-preferred brand name drugs vs. preferred generic drugs vs. non-preferred generic drugs vs. specialty drugs; you must know how to obtain your drugs from preferred in-network pharmacies vs. non-preferred in-network pharmacies vs. mail order pharmacies; and you must know whether your drugs are subject to any restrictions.

I spoke to one caller, a 66 year-old woman from Maryland, who was denied a request to lower the cost of an MS (Multiple Sclerosis) drug because it was classified in a specialty tier. She was forced to choose between paying more out of pocket for the medication or covering her other expenses. She lives on \$1,800 a month in Social Security benefits, which is too high for federal assistance from Part D's Extra Help program. She is not alone. Many of my callers need extremely expensive drugs, forcing them to make difficult decisions. Many beneficiaries have to split their pills despite their doctor's prescription, choose between purchasing food and purchasing medication, or stop taking their medications completely.

Part D has done many good things for older adults and people with disabilities, but there is much more that can be done to improve the program. Thank you for the opportunity to testify about my experience helping people with Medicare Part D.

The CHAIRMAN. Thank you, Dr. Woerner, and we are looking forward to some questions as we dig into this issue of the Medicare prescription drug benefit.

Dr. Hoadley.

**STATEMENT OF JACK HOADLEY, PH.D., RESEARCH PROFESSOR, HEALTH POLICY INSTITUTE, GEORGETOWN UNIVERSITY**

Mr. HOADLEY. Thank you, Mr. Chairman, and thank you, members of the Committee. I do appreciate this opportunity to talk about my ongoing research work on the record of Part D over the 10 years since the law was passed, and that is the occasion for this hearing.

Part D really marked several firsts in Medicare. It was the first outpatient drug coverage for Medicare beneficiaries, something that was not included in the original program; the first part of Medicare solely available through private plans and not part of the Fee-For-Service system; the first time Medicare had provided direct assistance to low-income beneficiaries not relying on Medicaid to provide that assistance; and an unusual benefits structure with a gap in coverage, also known as the donut hole.

As we look at the record of Part D over the time since it started, there are some important successes but some ongoing issues and concerns, and I want to mention a few of each; first, the successes.

The cost of Part D has been 30 percent lower than the initial budget projections, and that is a really important thing, something we do not often get to talk about. This is not so much a result, in my view, of plan competition as some have argued. But the program has been able to take advantage of the lower spending trend on prescription drugs over this period of time and the increased use of generic drugs as many of the popular drugs that people take have gone off formulary and have become available as generics. Lower enrollment has also been somewhat of a factor although not one of the ones that we should be so happy with.

A second success is that enrollees in Part D have had reduced out-of-pocket spending and increased access to their needed drugs, and the research record is really very supportive of this finding.

Third, Congress has taken steps to fix the most important design flaw in the program—that donut hole that I referred to earlier—and that is still on schedule to be phased out by 2020. That means that people are not running into the problems of having to stop their drugs when they hit that donut hole as they did before, and once it is phased out, that issue will really have gone away.

Fourth, the program's start back in 2006, despite a lot of initial concerns, went relatively smoothly. And while there were glitches along the way and glitches continue, in many cases during that initial rollout, problems were fixed and resolved, and we ended up with people enrolled in the program.

But issues do remain. Although Congress and the CMS have made important adjustments, there is still room for improvement, and again, I want to highlight four areas.

First, Part D remains complex and confusing to many beneficiaries as you just heard discussed a bit. Despite some really important CMS efforts to streamline the program, there are still too

many plans with too many complicated differences that are hard for people to understand.

People really regularly report that it is a confusing benefit. As a result, people do not always pick the plan that is best for them, and furthermore, they do not always look at alternative plans during the open enrollment period that might save them money and put them in a better situation.

Second, not every Medicare beneficiary has drug coverage. It appears from the best available data that 10 percent—1 in 10 beneficiaries—do not have adequate drug coverage, do not have Part D or some other equivalent coverage that is as good or better than Part D. We do not fully understand who those people are and why that has happened, but that is something we really need to redouble efforts to make sure everybody who needs that benefit really has access to it and gets it.

Third, there are some important issues remaining with the low-income subsidy program. It has been a very powerful program and a big help to people who get the subsidy, but of the people who have to apply on their own and do not automatically get the subsidy through Medicaid, only 40 percent of those required to apply actually have done so and gotten the low-income subsidy. So more than half of people that we think are eligible are not enrolled in the subsidy, and that means they are not getting the extra help they are entitled to.

Furthermore, those with the subsidy generally must switch plans on a fairly regular basis in order to gain all the benefits of the subsidy—for example, to keep a plan with no premium charge. Right now, we know that 1.6 million beneficiaries who are part of the low-income subsidy program are actually paying a premium to stay enrolled in Part D, something that they would not have to do if they were to switch to one of the eligible plans.

But even the fact of switching to other plans—and CMS does re-assign quite a few people each year—means that people's existing coverage is disrupted; they run into formulary issues, drugs that used to be covered that are not anymore and this sort of thing.

So there is a problem sort of with both ways, and again, there are things that we could probably do to address some of these things.

Fourth, although the cost has been below projections, spending trends in the future could add cost pressures. The wave of patent expirations that has been responsible for keeping spending down is slowing, and so that is going to mean we will not get the advantage of that in the future.

And a lot of the new drugs on the market tend to be expensive specialty drugs—drugs that come at a high price tag. They are important therapies, and beneficiaries need appropriate access to those drugs, but they are going to be expensive drugs.

And there are policy levers available, going everywhere from more availability of follow-on biologics—and there have been some steps taken in that direction—the potential to use the Part D rebates that the Chairman and others on the Committee have supported, and better medication therapy management by plan to try to make sure there is appropriate use of those drugs.

And I could add some of the points that Dr. Woerner talked about—about the appeals process.

The bottom line is that we can point to some clear successes in the program, but it is critical we not rest on the record of its success and address some of the outstanding issues.

And, just as one last point, let me observe that the experience in launching this program may also offer some really valuable lessons to the launch of the insurance exchanges this fall, and I would be glad to talk more about that in response to questions.

[The prepared statement of Mr. Hoadley follows:]

**Assessing Medicare Part D Ten Years After Enactment**

**Statement of  
Jack Hoadley, Ph.D.**

**Research Professor  
Health Policy Institute, Georgetown University**

**Before the  
Senate Special Committee on Aging**

**May 22, 2013**

Good afternoon, Mr. Chairman and Members of the Committee. My name is Jack Hoadley, and I am a Research Professor at Georgetown University's Health Policy Institute. As a long-time analyst of prescription drug issues, I have studied Medicare Part D since before it was created by the Congress. And I have published a wide variety of papers relating to this program. I appreciate the opportunity to speak to the Committee on the tenth anniversary of its creation.

**History of Medicare Part D**

The Medicare Part D prescription drug benefit today is in its eighth year of operation. As this hearing highlights, Part D became law ten years ago as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Enacted in a contentious, partisan environment with close votes in both the House and Senate, the MMA was signed into law by President George W. Bush on December 8, 2003.

The history of outpatient drug coverage in Medicare is far longer. By one account, such coverage was omitted from the original Medicare program in 1965 "on the grounds of unpredictable and potentially high costs."<sup>1</sup> Other opportunities to address outpatient drug coverage came and went until Congress added an outpatient drug benefit to Medicare as part of the Medicare Catastrophic Coverage Act of 1988. This benefit, which would have provided coverage after an initial \$600 deductible, never went into effect because the underlying legislation was repealed in 1989. President Bill Clinton included Medicare drug coverage in his unsuccessful effort to enact broader health reform legislation. Then in 1999, President Clinton proposed a Part D drug benefit. This proposal did not become law, but included many but not all of the elements that were part of the program that passed in 2003.<sup>2</sup>

As enacted in 2003, Medicare Part D marked several firsts. Not only was it the first program to offer outpatient prescription drug benefits to Medicare beneficiaries, but it was the first part of Medicare to be made available solely through competing private health plans, rather than being

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<sup>1</sup> Theodore R. Marmor, *The Politics of Medicare*, 2nd ed. New York: Aldine de Gruyter, 2000.

<sup>2</sup> For more information on the history of Medicare drug coverage, see Thomas R. Oliver, Philip R. Lee, and Helene L. Lipton, "A Political History of Medicare and Prescription Drug Coverage," *Milbank Quarterly* 82(2): 283-354, June 2004.

offered as part of traditional, fee-for-service Medicare. Part D also marked the first time that assistance for low-income beneficiaries was offered directly through Medicare, not through supplemental coverage provided through Medicaid. Although everyone is eligible for the Part D benefit without any type of means test, those at lower income levels are eligible for more highly subsidized coverage. As a result of later changes in law, those at higher income levels pay a premium surcharge.

The standard Part D benefit includes a deductible and beneficiary cost sharing. But it also includes the unusual feature of a coverage gap or “doughnut hole,” in which beneficiaries are required to pay the entire cost of their drugs. Those who make it through the gap become eligible for catastrophic coverage with more modest cost sharing. As a result of the Affordable Care Act, the coverage gap is currently being phased out and will no longer exist as of 2020. Plans offering Part D have the flexibility to modify the benefit design, within specified limits. Many plans eliminate the standard deductible, most plans substitute tiered cost sharing with flat copayments for the 25-percent coinsurance in the standard benefit, and most also include a specialty tier for selected high-cost drugs. In addition, some plans offer enhanced benefits, for example, to provide coverage for some drugs in the coverage gap or to reduce overall cost-sharing levels.<sup>3</sup>

#### **The Successes of Medicare Part D**

In several key respects, Part D can be considered a success, although several ongoing problems limit our ability to call the program an unqualified success. In the remainder of my testimony, I will outline the program’s successes and the ongoing issues. At the end, I will identify a few lessons that the Part D experience offers to the implementation of the health insurance exchanges (marketplaces) under the Affordable Care Act.

**Success: the cost of Part D has been lower than expectations.** A key element of the debate over the creation of Part D was the potential cost of the program. At the time of passage, the Congressional Budget Office (CBO) estimated the ten-year budget impact of the drug benefit as \$407 billion for fiscal years 2004 to 2013, while the Bush Administration’s estimates were 25 percent higher. Estimating these costs was challenging, since there was no precedent for the program’s stand-alone private drug plans. Trends in drug spending were also a concern, with annual growth at the time standing at around 12 percent – a combination of both price increases and higher utilization.<sup>4</sup>

The reality is that Part D spending has been considerably lower.<sup>5</sup> Based on spending numbers from the 2012 Medicare Trustees Report, total spending on Part D benefits and administration was about 74 percent of projected levels in the program’s first year (2006) and average 68 percent of

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<sup>3</sup> Jack Hoadley et al., *Analysis of Medicare Prescription Drug Plans in 2012 and Key Trends since 2006*, Issue Brief, Kaiser Family Foundation, September 2012; Jack Hoadley et al., *Medicare Part D: A First Look at Part D Plan Offerings in 2013*, Data Spotlight, November 2012.

<sup>4</sup> Jack Hoadley, *Medicare Part D Spending Trends: Understanding Key Drivers and the Role of Competition*, Kaiser Family Foundation, Issue Brief, May 2012. Similar conclusions have been noted elsewhere. Edwin Park, “Misleading Claim About Medicare Part D Relies on Faulty Arithmetic,” Blog posting, Center on Budget and Policy Priorities, June 12, 2012. Doug Elmendorf, “The Accuracy of CBO’s Budget Projections,” CBO Blog, March 23, 2013.

<sup>5</sup> Jack Hoadley, *Medicare Part D Spending Trends: Understanding Key Drivers and the Role of Competition*.

projections over the first six years. In 2011, actual program spending was \$60 billion dollars, compared to the projected level of \$95 billion. Several factors have contributed to lower total costs.

- Initial program enrollment was significantly below projected levels in 2006. Enrollment growth from year to year, however, has been at projected levels.
- The growth of drug spending across all payers (public and private) has been considerably slower than projected. CBO had projected 12 percent growth per capita between the law's passage and the 2006 start of the benefit and 9 percent per capita thereafter. In fact, the actual trend has been 10 percent and 4 percent, respectively.
- The start of Part D coincided with patent expirations for many of the most commonly prescribed drugs – sometimes referred to as the “patent cliff” – and the relatively slow pipeline for new drugs. The share of generic drugs for Part D enrollees rose from 60 percent in 2006 to 75 percent in 2010, and is higher today. Because the cost of the average generic drug is about 25 percent of the chemically equivalent brand-name drug, higher generic use translates into lower drug spending.
- Based on available evidence, claims that spending is lower because of the program's use of competing private plans seem overstated. Plans' management of the Part D benefit may have helped to encourage greater use of generic and other lower-cost drugs, but broader trends across the health system have been more important.

**Success: Part D has reduced costs and increased access for enrollees.** Without drug coverage, people are more likely to skip some necessary drugs and to take others less frequently than prescribed.<sup>6</sup> The acquisition of drug coverage through Part D has meant that use of drugs grew considerably for those without a prior source of coverage.<sup>7</sup> It has also reduced the amounts that enrollees pay out of pocket to obtain needed drugs. Although more research is needed, there is some evidence that increased use and adherence to medications by Part D enrollees is saving money elsewhere in Medicare as a result of fewer hospitalizations and less use of other services.<sup>8</sup>

<sup>6</sup> Patricia Neuman et al., “Medicare Prescription Drug Benefit Progress Report: Findings from a 2006 National Survey of Seniors,” *Health Affairs* 26(5): w630-w643, August 21, 2007; Stephen B. Soumerai et al., “Cost-Related Medication Nonadherence among Elderly and Disabled Medicare Beneficiaries: A National Survey One Year before the Medicare Drug Benefit,” *Archives of Internal Medicine* 166(17): 1829-1835, September 25, 2006.

<sup>7</sup> Jennifer M. Polinski et al., “Changes in Drug Use and Out-of-Pocket Costs Associated with Medicare Part D: A Systematic Review,” *Journal of the American Geriatrics Society* 58(9): 1764-1779, September 2010; Jennifer M. Polinski et al., “Medicare Part D's Effect on the Under- and Overuse of Medications: A Systematic Review,” *Journal of the American Geriatrics Society* 59(10): 1922-1933, October 2011; Sebastian Schneeweiss et al., “The Effect of Medicare Part D Coverage on Drug Use and Cost Sharing among Seniors without Prior Drug Benefits,” *Health Affairs* 28(2): w305-w316, February 3, 2009; Wesley Yin et al., “The Effect of the Medicare Part D Prescription Benefit on Drug Utilization and Expenditures,” *Annals of Internal Medicine* 148(3): 169-177, February 5, 2008; Jeanne M. Madden et al., “Cost-Related Medication Nonadherence and Spending on Basic Needs Following Implementation of Medicare Part D,” *JAMA* 299(16):1922-1928, April 23/30, 2008; Jeanne M. Madden et al., “Cost-Related Medication Nonadherence After Implementation of Medicare Part D, 2006-2007,” *JAMA* 302(16):1755-1756, October 28, 2009; Dana G. Safran et al., “Prescription Coverage, Use and Spending Before and After Part D Implementation: A National Longitudinal Panel Study,” *Journal of General Internal Medicine* 25(1): 10-17, January 2010.

<sup>8</sup> J. Michael McWilliams et al., “Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage,” *JAMA* 306(4): 402-409, July 27, 2011; Christopher C. Afendulis et al., “The Impact of Medicare Part D on Hospitalization Rates,” *Health Services Research* 46(4): 1022-1038, August 2011; Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services*, November 2012.

**Success: A big design flaw in Part D – the coverage gap – is being fixed.** In the Affordable Care Act, Congress addressed one of the least-liked features of Part D and one that is unique to this program. The coverage gap is not well understood by enrollees, but one in five Part D enrollees typically reaches the gap in any one year and experiences higher out-of-pocket costs. Many enrollees in this situation respond by stopping some of their prescribed drugs or by taking them less often.<sup>9</sup> It is harder to know whether this reduction in use has health consequences.<sup>10</sup> The Affordable Care Act's reduction of the gap started in 2011 with lower beneficiary costs for brand-name drugs. By 2020, enrollees will face the same cost sharing at the spending levels now associated with the gap as they do at lower spending levels.

**Success: The program's launch, despite initial concerns, went relatively smoothly.** On the eve of the program's first open enrollment period, there was considerable wariness and skepticism that the program launch would occur as designed. Would drug plans be offered, or would fallback plans, part of the original law, be necessary?<sup>11</sup> Would the Centers for Medicare & Medicaid Services (CMS) and its partners succeed in educating potential enrollees about the new benefit? Would information systems needed for enrollment and subsidy operate effectively? Would people sign up for the new benefit? When the initial open enrollment period ended on May 15, 2006, 22.5 million Medicare beneficiaries had enrolled in Part D plans, and another 7 million remained in employer-sponsored retiree coverage with a federal subsidy. While about 9 million beneficiaries retained coverage from another source (for example, through the Veterans' Administration), about 4.5 million, or about 10 percent of all beneficiaries, remained with no source of coverage.

The program's launch was not without glitches that included errors in the online Plan Finder, unanswered calls to Medicare and plan call centers, confusion on the part of potential enrollees, and problems getting needed drugs at the right price at the pharmacy counter. In many cases where problems were found, federal and state officials responded quickly to correct mistakes, add staff at call centers, provide counseling, and ensure that temporary supplies of drugs were dispensed.<sup>12</sup>

#### Outstanding Issues for Medicare Part D

Notwithstanding these successes, however, issues remain. Congress and CMS have made adjustments to lessen some of the outstanding concerns, but there is still room for improvement.

**Issue: Part D remains complex and confusing to many beneficiaries.** Many beneficiaries still think there are too many plans to choose from in Part D. CMS has taken some important steps to eliminate plans with low enrollment and to require that multiple plans offered by the same plan sponsor are meaningfully different from each other. But on average, each Medicare beneficiary still has a choice of 31 stand-alone drug plans – even more in areas where there are many Medicare

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<sup>9</sup> Jack Hoadley et al., *Understanding The Effects of The Medicare Part D Coverage Gap in 2008 and 2009*, Kaiser Family Foundation, August 2011.

<sup>10</sup> Geoffrey F. Joyce et al., "Digested the Doughnut Hole," *Journal of Health Economics*, accepted manuscript, 2013.

<sup>11</sup> To address the possibility that no private plan sponsors would enter the market to offer stand-alone drug plans for beneficiaries enrolled in traditional Medicare, the law provided for a fallback option offered directly through the government in any region failing to meet the threshold of two plans being available.

<sup>12</sup> Mark McClellan, CMS, "Implementation of the New Medicare Prescription Drug Benefit, testimony to the Senate Committee on Finance, February 8, 2006

Advantage plans.<sup>13</sup> In selecting a plan, beneficiaries must consider benefit and formulary differences, cost levels, and plan reputations. In recent years, the increased use of preferred pharmacy networks has introduced an additional element to be considered in selecting plans. Several studies have shown that enrollees fail to select a plan that would keep their costs as low as possible.<sup>14</sup> Furthermore, the program's complexity encourages many enrollees to stick with their current plans even when a switch could save considerable money.

**Issue: Not every beneficiary has drug coverage.** According to the best available counts, 10 percent of Medicare beneficiaries remain without drug coverage in Part D or some other source of equivalent or better coverage. We lack good information on why these people have no coverage. While some in this group likely are making rational decisions to forgo coverage, it is important to reach out to all beneficiaries and determine whether others are unaware of the help they could receive from Part D.

**Issue: Some beneficiaries who are eligible for the Low-Income Subsidy (LIS) are not signed up.** The Low-Income Subsidy in Part D is helping about 11 million Medicare beneficiaries obtain assistance with the cost of drug coverage. Many get this extra help automatically as a result of receiving benefits from Medicaid (dual eligible), Medicare Savings Programs (MSP), or Supplemental Security Income (SSI). But only 40 percent of eligible low-income beneficiaries who are not automatically enrolled by CMS enrolled for the LIS in 2009 (the most recent estimate available).<sup>15</sup> In addition, about 1.6 million beneficiaries with the LIS unnecessarily pay a premium for the Part D coverage because they have not selected one of the qualifying benchmark plans.<sup>16</sup> Many of them pay at least \$10 per month, and some pay much more. This is in addition to about 900,000 beneficiaries who were reassigned by CMS during the most recent open enrollment season to avoid falling into this situation. The advantage of a reassignment or voluntary plan switch is that it avoids the situation of paying a monthly premium for drug coverage; the drawback is that it means a disruption of one's current coverage. A new plan usually means new formularies and new coverage rules, new procedures, and a different pharmacy network. The Congress and CMS have taken steps to increase the number of benchmark plans that are available, but other changes are needed. Although the LIS has been an enormous help to many low-income Medicare beneficiaries, critical design improvements could make this program even more effective.

**Issue: Higher spending trends could increase future cost pressures.** Although Part D costs to date have been considerably lower than the original projections, lower costs have resulted in great part from the patent cliff and the substitution of low-cost generic drugs for brand-name alternatives. We will soon reach the point where most commonly used drugs are available as generics or at least

<sup>13</sup> Jack Hoadley et al., *Medicare Part D: A First Look at Part D Plan Offerings in 2013*, Data Spotlight, November 2012.

<sup>14</sup> Yaniv Hanoch et al., "Choosing the Right Medicare Prescription Drug Plan: The Effect of Age, Strategy Selection, and Choice Set Size," *Health Psychology* 30(6):719-727, November 2011; Jason Abaluck and Jonathan Gruber, "Choice Inconsistencies among the Elderly: Evidence from Plan Choice in the Medicare Part D Program," *American Economic Review* 101(4): 1180-1210, June 2011.

<sup>15</sup> Laura Summer, Jack Hoadley, and Elizabeth Hargrave, *The Medicare Part D Low-Income Subsidy Program: Experience to Date and Policy Issues for Consideration*, Kaiser Family Foundation, September 2010.

<sup>16</sup> Benchmark plans are drug plans that are available for no monthly premium to LIS enrollees, defined as below a regional average premium. Jack Hoadley et al., *Analysis of Medicare Prescription Drug Plans in 2012 and Key Trends since 2006*, Issue Brief, Kaiser Family Foundation, September 2012.

have a generic alternative in the same drug class. As forecast by both CBO and CMS, drug cost growth is likely to be higher in the coming years, although not as high as in the 1990s. The larger role played by biologics and other specialty drugs – typically with prices far higher than conventional drugs – will likely contribute to this higher growth. These new drugs may offer important treatments, especially for some health conditions lacking effective medications today. But managing this cost growth will be critical to keeping the program affordable for both plan enrollees and taxpayers. The regulatory approval of follow-on biologics (a process starting with the new approach that became law in the Affordable Care Act) offers one route to controlling the cost of these drugs. But ensuring that newly approved follow-on biologics will be accepted and used by patients and their physicians will require further steps. The proposal introduced recently by several members of Congress, including the Chairman of this Committee, for a new federal Part D rebate for drugs purchased by LIS beneficiaries offers another means of addressing the cost of expensive drugs. Development of more robust medication therapy management (MTM) programs by Part D plans could also help to ensure appropriate use of high-cost medications. At the same time, it is vital that high cost sharing for specialty drugs does not create an impediment for the appropriate and timely use of these drugs and prevent the health benefits of their use.

#### **The Bottom Line for Part D and Lessons for Insurance Exchanges**

In the ten years after the Medicare Part D program was created by the Congress, we can point to some clear successes. More Medicare beneficiaries are able to take prescription drugs that may be improving their health and extending their lives. They are spending less out of pocket, meaning they are not forced to make difficult choices between medications and other needs. Many low-income beneficiaries receive extra help beyond the basic help available to all beneficiaries. Thanks to a lower growth rate for drug spending, we have accomplished these results at a cost lower than originally projected.

But it is critical that we not rest on this record of success. Steps should be taken to ensure that new cost pressures, such as those posed by expensive specialty drugs, do not challenge the program's affordability in the future. Steps should also be taken to ensure that every Medicare beneficiary who is eligible for both Part D and its Low-Income Subsidy has a real opportunity to participate. Recent actions by the Congress and the Administration have helped to improve the benefit by phasing out the coverage gap and simplifying the program, but further changes can help make sure that Part D enrollees get access to needed drugs without paying unnecessary costs out of pocket.

Finally, let me observe that the successful launch of Medicare Part D offers lessons to the launch of insurance exchanges later this year. In 2005, there was considerable concern wariness and skepticism that the government could get Part D started in time for the program's first day on January 1, 2006. Indeed numerous issues did arise during the initial enrollment period and when beneficiaries visited pharmacies for the first time to use the new benefit. But in many cases, officials at CMS and in the states as well as other stakeholders found ways to address problems with short-term fixes. And as described in my testimony, both the Congress and CMS have made further improvements since that time. We should be mindful of the Part D experience as implementation of insurance exchanges moves forward this year.

The CHAIRMAN. Dr. Hoadley, thank you for the value of your research.

Mr. Smith.

**STATEMENT OF RICHARD SMITH, EXECUTIVE VICE PRESIDENT FOR POLICY AND RESEARCH, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA**

Mr. SMITH. Mr. Chairman, Ranking Member Collins and members, good afternoon.

Medicare Part D has been highly successful. And, like my colleagues, I will come to a few points where we believe improvements can be made, and some of those will echo the points they have made, but overall, it has been highly successful.

Nine in ten seniors have drug coverage. Ninety-four percent are satisfied with their coverage as reported by MedPAC.

Program costs are 45 percent less than initially projected as we have worked with the CBO data, and average monthly premiums, which remained at about \$30 from 2011 through 2013, are half the original forecast.

Medicines, of course, play a central role in fighting disease, especially for seniors. Yet, they are a modest part of health spending. Part D accounted for only 10 percent of Medicare costs in 2012.

In addition, growth in spending has been acknowledged. Growth in spending on medicines has undergone a sharp and sustained slowdown in recent years. In each of the last 3 years, CBO has reduced its 10-year forecast for Part D by over \$100 billion.

And Part D is responsible for much of the overall slowdown in Medicare spending. Further, CMS says its spending per person in Part D will grow 1.8 percent in 2013, and marketwide, 4 of the 5 years with the lowest prescription drug spending growth have occurred since Part D began in 2006.

One reason for slow growth in drug costs is the prescription drug life cycle in which brand companies develop medicines which later become generics, and here, I have a slight disagreement with my co-panelist. I believe that the market works to obtain maximum savings from the life cycle.

Four out of five prescriptions are now filled with generics, and this system is unique to medicines. It contains costs and allows resources to be reallocated from older to newer treatments. Due to the life cycle, between 2006 and 2010, the average cost per day in 10 commonly used classes of medicines in Part D dropped from \$1.50 to \$1.00.

Medicines can also help reduce other health costs. In November, CBO announced it will credit policies that increase use of medicines with savings on other Medicare services. In making this change, CBO cited research finding that in its first full year Part D reduced nondrug medical costs for beneficiaries who previously had no or limited coverage by an average of \$1,200. This equaled about \$13 billion in savings in 2007.

And new research suggests even greater potential. For instance, increased adherence with medicines for congestive heart failure could save Medicare \$22 billion in the coming decade.

Part D's competitive structure is a large part of the reason for its success. Part D plans bid competitively. These organizations al-

ready buy drugs on behalf of tens of millions of people in the commercial sector and use their clout and specialized expertise to negotiate discounts that lower Part D premiums and beneficiary cost-sharing. And, likewise, beneficiaries have an incentive to pick plans with low premiums and good coverage.

And I will be glad to come back and address that in questions.

Some suggest that more savings could come from Part D through government negotiation. We disagree. Because of the robust price negotiations by private plans already built into the program, CBO has consistently found that giving the government authority to negotiate would have a negligible effect on Federal spending unless the Secretary imposed new restrictions on access to medicines.

Some have also proposed that imposing Medicaid's price controls are mandated rebates on medicines used by low-income Medicare beneficiaries. Proponents of this suggest it would simply be a return to the pre-Part D status quo, and I believe that is not accurate.

First, the policy, as proposed, would apply to millions of people who were never eligible for Medicaid drug coverage.

Second, Part D extended negotiated discounts to 11 million people who previously did not have them. It also increased generic use and led to new cost containment tools that have now been spread throughout the market.

Third, there have been major policy changes since 2006. The BIO-PhRMA sector now pays a higher Medicaid rebate, a fee to the Medicaid Trust Fund and 50 percent discounts in the coverage gap. Analysts estimate these new costs add over \$100 billion over 10 years.

And analysts, including a former CBO director and former CMS chief actuary, see mandated rebates as leading to higher premiums fewer plan choices and more restrictive formularies in Part D.

Researchers have also found that price controls would discourage R&D investment in new medicines at great cost to private health, and CBO has noted that Part D rebates could discourage R&D investment in medicines mostly used by seniors.

The U.S. leads the world in drug development, and the BIO-PhRMA sector is one of the most R&D-intensive in the economy, accounting for 20 percent of all business-funded R&D in the United States. In addition to improving medicines that improve lives, R&D is widely recognized as driving economic growth.

I will conclude by noting that, like any program, improvements could be made in Part D. For instance, not all eligible individuals are enrolled, as my colleagues have pointed out. Seniors could be encouraged to shop more among plans and be supported in that shopping to make good choices. And there could be improvements in medication therapy management in the specialty tier. However, program improvement should not undermine the hallmarks and successes of Part D.

Continued innovation is challenging. There is a lot more to be done. Consider that without new treatments to alter the course of the disease, Alzheimer's will cost Medicare and Medicaid \$300 billion annually by 2030. None of us want that to happen. So hope for the future lies with continued innovation.

And I appreciate your invitation to testify.

[The prepared statement of Mr. Smith follows:]

TESTIMONY OF RICHARD I. SMITH  
EXECUTIVE VICE PRESIDENT, POLICY AND RESEARCH  
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

BEFORE THE U.S. SENATE SPECIAL COMMITTEE ON AGING

MAY 22, 2013

Chairman Nelson, Ranking Member Collins, and Members of the Committee, thank you for inviting me to testify on the Medicare prescription drug program, also known as Part D.

**Drug Discovery and Better Health**

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. The Congressional Budget Office (CBO) reports that the pharmaceutical sector is one of the most research-intensive industries in the United States, investing as much as five times more in research and development than the average U.S. manufacturing firm.<sup>1</sup> According to the National Science Foundation, biopharmaceutical companies account for about \$1 out of every \$5 of industry research and development (R&D) undertaken in the U.S.<sup>2</sup> Since 2000, PhRMA member companies have invested approximately \$550 billion in the search for new treatments and cures for disease.<sup>3</sup>

This investment in the discovery and development of new medicines has produced numerous medical advances that have changed the course of disease and the face of medical care. The breadth and scope of these advances is far too great to comprehensively describe. A few examples follow of the dramatic impact medicines have made in the fight against cancer, cardiovascular disease, HIV/AIDS, and hepatitis C:

- Since 1988, life expectancy for cancer patients has increased about 4 years, with roughly 80% of those gains attributable to new treatments, including medicines.<sup>4</sup> Increases in life expectancy for cancer patients between 1988 and 2000 yielded 23 million additional life years and roughly \$1.9 trillion of additional social value, four-fifths of which accrued to patients.<sup>5</sup> Further, between 2000 and 2011, cancer deaths have fallen by 15.5%.<sup>6</sup> These medical advances have a profound impact on seniors, who account for more than half of all new cancer cases.<sup>7</sup>
- Cardiovascular disease represents a significant disease burden today; an estimated 82.6 million adults are living with one or more types of cardiovascular disease, and the prevalence of heart disease is nearly three times higher in seniors compared to other age groups.<sup>8</sup> However, due to the benefits of biomedical innovation, the death rate for cardiovascular disease fell 33% just between 1999 and 2009.<sup>9</sup> In the words of

researchers at Johns Hopkins University, “protein enzymes, receptors, or channels identified by the pharmaceutical industry as ‘drugable targets’ have led to striking, remarkable, and repeated achievement.”<sup>10</sup> Leading researchers estimate that just one class of cardiovascular medicines – statins – yielded about 40,000 fewer deaths and 82,000 fewer hospitalizations for heart attack and stroke in 2008. Harvard researcher David Cutler has found that “Reduced disability associated with cardiovascular disease accounts for a significant part of the total reduction in disability [among community dwelling Medicare recipients]—between 19 and 22 percent. The evidence suggests that improvements in medical care, including both increased use of relevant procedures and pharmaceuticals, led to a significant part of this decline.”<sup>11</sup>

- In today’s world, an HIV/AIDS diagnosis is no longer considered a death sentence. Since the approval of antiretroviral treatments in 1995, the HIV/AIDS death rate has dropped by 85%.<sup>12</sup> According to leading HIV researchers, “In stark contrast to the early and mid-1980s, if a person aged 20 years is newly infected with HIV today and guideline recommended therapy is initiated, researchers can predict by using mathematical modeling that this person will live at least an additional 50 years — that is, a close-to-normal life expectancy.”<sup>13</sup>
- The treatment of hepatitis C is another important example of how new medicines can profoundly change the course of a disease that affects several million Americans and tens of millions around the globe. The chance that a patient would reach the goal of sustained virologic response (undetectable virus for 24 weeks after treatment) was about 10% in the 1990s and, with new medicines, improved to about 40% in the early- to mid-2000s. Two years ago, the introduction of protease inhibitors and triple therapy regimens revolutionized treatment for hepatitis C, increasing sustained virologic response to about 75%, depending on prior treatment experience.<sup>14-15</sup> These treatment advances are expected to halt the progression to end stage liver disease, reduce the need for liver transplantation, and prevent complications such as hepatocellular cancer, which will likely result in fewer deaths from the virus and avoided health care costs. Continuing innovation in hepatitis C treatments include new therapies on the horizon that have the potential to be even more efficacious, have improved safety profiles and be more convenient for patient use.

#### **The U. S. Biopharmaceutical Research Sector and the Economy**

The U.S. biopharmaceutical research sector leads the world in the development of new medicines, with more than 3,200 medicines in development or FDA review in the U.S. According to a 2011 Battelle study supported by PhRMA, the sector generates high-quality jobs and powers economic output and exports for the U.S. economy, serving as the “the foundation upon which one of the U.S.’ most dynamic innovation and business ecosystems is built.”<sup>16</sup>

These jobs encompass the research-based occupations that will help sustain future U.S. economic growth, often requiring specialized science, technology, engineering, and math (STEM) skills. The U.S. biopharmaceutical sector directly provides more than 650,000 jobs, but supports a total of 4 million jobs across the economy. In 2009, the biopharmaceutical sector contributed \$917 billion to the economy when considering direct, induced, and indirect effects.<sup>17</sup>

These economic impacts are driven by the R&D enterprise, in which PhRMA member companies alone invested an estimated \$48.5 billion in 2012,<sup>18</sup> with most of these investments made in the U.S. The pharmaceutical sector was responsible for almost 20% of all U.S. business-funded R&D investment in 2008, a larger share than any other industrial subsector, with biopharmaceutical spending nearly twice as much on R&D as the automotive and aerospace industries combined.<sup>19</sup> Biopharmaceutical companies invest more than ten times the amount of R&D per manufacturing job compared to manufacturing industries overall.<sup>20</sup>

The President's Council of Advisors on Science and Technology recognized that the "nation's leadership in biomedical innovation has been supported by a robust industry, and, in turn, investments in biomedical research and corresponding medical advances have allowed industry and the economy to thrive. Biomedical innovation has supported U.S. economic growth, and high-value, high-skilled jobs for Americans."<sup>21</sup>

This sector, which drives science, medical advances and high quality jobs (with its R&D intensity driving its high multiplier effect on jobs throughout the economy), was not always centered in the U.S. Thirty years ago, Europe produced more than half of the intellectual property related to new medical compounds. Now, Europe represents roughly a quarter while the U.S. accounts for more than half.<sup>22</sup> Over the same timeframe the number of new drug approvals which were U.S. in origin increased while the percentage that were European in origin remained static. According to Günter Verheugen, formerly Vice-President of the European Commission responsible for Enterprise and Industry, Europe's loss of leadership in R&D in life sciences to the U.S. was due in part to the lack of a predictable and stable regulatory system and other policies that did not favor innovation.<sup>23</sup>

The U.S. is recognized as the global leader in biopharmaceutical R&D. Burrill and Company reports that U.S. health biotechnology companies account for 80% of global health biotechnology R&D.<sup>24</sup> A large part of the economy is built upon a robust foundation of innovative biopharmaceutical companies that perform and support advanced R&D, and act as a funnel and distribution engine for getting life-saving and quality-of-life sustaining medicines to patients. To sustain this innovation requires a supportive policy environment.

#### **Trends in Spending for Prescription Medicines; Opportunities for Savings**

At the same time that medicines have been making extraordinary progress against disease, they account for a small share of health spending. For instance, an analysis by Avalere Health

projects that between 2011 and 2019, brand medicines will account for approximately 8% of federal spending on Medicare and Medicaid.<sup>25</sup>

In addition to medicines' low share of overall health spending, growth in spending on medicines has slowed dramatically over the last decade. Recently, IMS Health reported that after years of historically low growth (averaging 3.4% annually for the past five years), spending on prescription medicines declined in both absolute terms and on a per capita basis in 2012.<sup>26</sup> As IMS states, "The 'cost curve' for medicines—if not for other elements of the U.S. healthcare system—was bent."<sup>27</sup> Spending on brand medicines alone decreased by 5%. IMS projects that future growth in prescription drug spending will remain at historically low levels, averaging 1% to 4% between 2012 and 2016.<sup>28</sup>

Historical data from the Center for Medicare & Medicaid Services' Office of the Actuary (OACT) paints a similar picture. OACT's most recent data show that retail prescription drug spending grew by 0.4% in 2010 and 2.9% in 2011, while overall health spending grew by 3.9% in both years. Notably, four of the five lowest growth rates in spending on medicines OACT has reported over the past 50 years have occurred since 2006, the year Part D was implemented.

The trends in prescription medicine spending are the result of many factors, including several that are unique to the biopharmaceutical sector. Medicines are mostly purchased in a national market by very large, powerful, sophisticated purchasers who specialize in buying medicines and making aggressive use of various tools to achieve savings, driving utilization to the medicines for which they can negotiate the lowest prices.

Related to all of these factors is the prescription medicine lifecycle. In this lifecycle, innovator pharmaceutical companies produce medical advances through pioneering scientific work and large-scale investments, leading over time to generic copies that patients use at low cost for many years. Savings from generics are possible only because the medicine was previously invented by an innovator company, and the marketplace is quick to take up use of generics when they become available. This process provides built-in cost containment not available in other health sectors by continuously freeing up resources and reallocating spending from older to newer medicines. Although savings from the market's aggressive leveraging of the prescription medicine lifecycle are often ignored in policy debates discussing cost savings, the lifecycle is a central characteristic of the market for prescription medicines. Today, generic drugs account for 84% of all prescriptions filled in the U.S.<sup>29</sup>.

While prescription medicines are typically singled out and treated as a line-item in cost containment efforts, there is an extremely robust academic literature finding that use of medicines can help save money on other health care services, especially hospitalizations and emergency department care. For instance:

- Every additional dollar spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes or high cholesterol generates \$3 to \$10 dollars in savings on emergency room visits and inpatient hospitalizations.<sup>30</sup>
- Improving adherence to diabetes medicines could prevent 341,000 hospitalizations and 699,000 emergency department visits each year, resulting in annual savings of almost \$5 billion.<sup>31</sup>
- Greater adherence to statins could reduce total health care spending by more than \$3 billion annually by reducing avoidable cardiovascular disease-related hospitalizations.<sup>32</sup>

The opportunity for better health and savings on chronic illnesses through appropriate use of medicines is described by Harvard researcher Will Shrank and colleagues:

[P]atients frequently are not prescribed essential chronic medications and frequently fail to adhere to them when they are prescribed; both of these issues have major consequences for public health. A national chart-based review of the quality of care in the United States indicated that patients receive essential chronic medication therapy only about half the time...Numerous other studies have shown that patients with chronic conditions such as coronary artery disease, hypertension, diabetes and hypercholesterolemia only adhere to 50% to 60% of medications as prescribed despite conclusive evidence that medication therapy can substantially improve life expectancy and quality of life. Medication nonadherence alone is estimated to increase healthcare costs by more than \$170 billion annually in the United States. Efforts to stimulate better prescribing of and adherence to essential medications will increase value by improving population health, averting costly emergency department visits and hospitalizations, and improving quality of life and productivity.<sup>33</sup>

#### **Creation of Medicare Part D**

While medicines play a central role in today's health care system, prior to 2006 there was no outpatient prescription drug benefit through Medicare. Before Part D, about 30% of Medicare beneficiaries lacked any drug coverage<sup>34</sup> and many more had very limited coverage. There was widespread recognition by Members of Congress, the Administration, and advocates that the absence of a central part of modern medical treatment from Medicare coverage was resulting in poor health outcomes that could be avoided<sup>35</sup> and financial strain on beneficiaries (resulting from both the lack of prescription drug coverage and the lack of negotiated discounts for those without coverage). As a result, after many years of bipartisan efforts, Congress enacted legislation adding a prescription drug benefit to Medicare in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

The Part D program at the heart of MMA was structured to provide Medicare beneficiaries access to medicines through a choice among private plan offerings operating under a set of

program standards with government oversight. At the time of its development, there was some skepticism about many aspects of the program design, including questions about whether private plans would participate, whether beneficiaries would choose to enroll in the benefit or be satisfied if they did, whether premiums would be affordable, whether costs would be contained, and whether better use of medicines would yield savings on other health care costs. The program's track record – nearly ten years after enactment – answers these questions. The vast majority of eligible Medicare beneficiaries did enroll in Part D. Private plan participation in the program has always been robust. Beneficiaries have consistently reported high satisfaction with Part D. The program has contained premiums and overall costs far below original estimates. And Medicare coverage for prescription drugs has produced savings in other parts of the Medicare program.

*Part D Plan Participation*

A guiding principle in designing Part D was that beneficiaries should have choice among plans, to find one that meets their individual cost and coverage needs. Initial concerns that private plans would not serve some or even perhaps any areas of the country led policymakers to incorporate in the law government-run fallback drug plans that would be established if an insufficient number of plans stepped forward. However, plan participation has been robust and the government fallback plans have never been implemented. Today over 35 million people have drug benefits through Medicare,<sup>36</sup> and beneficiaries in every region have at least 23 plans from which to choose.<sup>37</sup>

*Beneficiary Experience with Part D*

From the beneficiary perspective, Part D has made premiums and medicines affordable, and has improved access and utilization, leading to better health outcomes. Given this, it is not surprising that 94% of Part D enrollees report that they are satisfied with their drug coverage and 95% are confident that the level of coverage meets their needs.<sup>38</sup>

By the end of 2006, over half of previously uninsured beneficiaries enrolled in Part D.<sup>39</sup> While not all eligible beneficiaries enrolled, the take-up rate was high and well-above that typically experienced in voluntary programs. Those who did enroll had greater health needs than those who did not.<sup>40</sup>

Beneficiaries who previously did not have drug coverage realized a large reduction in out-of-pocket (OOP) spending on medicines, because they gained access to insurance plus plan-negotiated discounts. This reduction in beneficiary OOP cost improved access to and utilization of recommended medicines among beneficiaries, particularly the newly insured. For example, a study supported by PhRMA found that the share of beneficiaries reporting difficulty paying for prescriptions dropped by two-thirds among low-income subsidy (LIS) beneficiaries -- from almost 29.7% reporting difficulty in 2005 to 9.5% in 2007. Similarly, among non-LIS beneficiaries who were previously uninsured, such difficulty dropped by about half (21.3% to 10%).<sup>41</sup> This data predates the establishment of coverage gap discounts.

Average beneficiary premiums have been lower than projected in each year of the program and have remained virtually flat over the last three years at \$30 per month.<sup>42</sup> Notably, while the parameters of basic coverage for Part D are defined in law, plans are permitted to vary the benefit offerings so long as the plan they offer is equal in value to the defined standard and certain additional criteria are met. Allowing such variation has benefitted enrollees. Today, only 4% of beneficiaries have chosen Part D plans whose coverage parameters match those in statutorily defined standard coverage; the rest have chosen an alternative design.<sup>43</sup>

There is still much room to improve utilization patterns, which would yield better health outcomes and additional savings – but Part D has been a large step forward.

*Part D Cost Containment*

Part D has far lower total costs than originally projected and there have been continuing large reductions in projected costs up to the present. According to the latest CBO data, Part D is on a track to cost \$348 billion (45%) less than projected for the initial 2004-2013 forecast period.<sup>44</sup> According to CBO figures, actual spending for Part D in 2012 – the latest year for which actual spending is available – was \$55 billion. This is 55% lower than the initial 2004 baseline spending forecast for that year. Additionally, CMS announced earlier this spring that Part D's per capita costs would rise only 1.83% for 2013, the lowest growth rate in the history of the program.<sup>45</sup>

While it has been widely reported that actual costs for the Part D program today are far below initial forecasts, less well known but equally important is the fact that Part D spending forecasts have continued to fall up to the present as the program has gained a longer track record. For example, CBO data shows that actual spending for 2012 was 20% lower than the forecast made just two years prior, in 2010, when significant legislative changes were made to the program.<sup>46</sup> Notably, CBO has reduced its 10-year projection for Part D spending by over \$100 billion in each of the last three years.<sup>47</sup> Given that there is extensive operational experience with the program, these reductions are clearly unrelated to the uncertainties underlying the initial forecast but instead relate to the continued pattern of low per capita growth, which has been lower than predicted year after year.

The size of the reduction in predicted spending for Medicare Part D has had a dramatic impact on CBO's predicted spending for all of Medicare. This is even more noteworthy given that Part D accounts for only 10% of total Medicare spending in 2012<sup>48</sup> (this includes brand and generic ingredient cost, health plan cost, and pharmacy cost). In releasing its annual Budget and Economic Outlook report in February this year, CBO noted that “the largest downward revision in the current [Medicare] baseline is for spending for Medicare's Part D (prescription drugs).”<sup>49</sup> CBO's current prediction for total Medicare spending in 2013 is now 9% lower than initially projected in 2004, and the reduction in Part D spending is larger than this total reduction. While

predicted spending for the rest of Medicare has increased relative to the forecast made in 2004, CBO's Part D spending projections have fallen by 54% over that period.<sup>50</sup>

*Better Use of Medicines Leads to Savings on other Medicare Costs*

At the time Part D was being developed, CBO expressly rejected calculating any savings in other parts of Medicare based on better access to medicines.<sup>51</sup> Since that time, a significant and growing body of research has developed showing that the use of prescribed medicines generates offsetting savings through reduced use of other medical services in the Medicare program. This body of evidence has profound implications for Medicare.

As the evidence of cost offsets from medicines has mounted and as more seniors and disabled Americans have gained better access to prescription coverage through Part D, in November of 2012 CBO announced a change to its cost estimating methodology to reflect "a substantial body of evidence" showing that increases in prescription drug use lead to offsetting reductions in spending for other Medicare medical services.<sup>52</sup> Among the research CBO cited was an article published in the *Journal of the American Medical Association* finding that implementation of the Medicare prescription drug program was followed by a \$1,200 average decrease in nondrug medical spending in both 2006 and 2007 among those who previously had limited drug coverage.<sup>53</sup> Other researchers have associated this reduction in non-drug spending with achieving approximately \$13.4 billion in overall savings during the first full year of Part D.<sup>54</sup> CBO also cited a study by Harvard researchers, with support from PhRMA, showing that introduction of Medicare Part D significantly reduced the probability of hospitalization for eight conditions, leading to 4% fewer hospital admissions, or an estimated 77,000 fewer annual admissions nationally.<sup>55</sup>

Just as the evidence has developed over time to support the consensus view that that medicines yield offsetting savings on other health care services, further development of the evidence will likely yield recognition of even larger savings than credited today. In its November report, CBO acknowledges that literature specific to a range of conditions shows medicines yielding larger offsetting savings than now built into CBO rules.<sup>56</sup> Preliminary findings from research in development supported by PhRMA suggests that the magnitude of offsetting savings for patients suffering from congestive heart failure, diabetes and several other conditions may be three to six times higher than the population average reported by CBO. It will be important to closely monitor the development of the evidence base in this area.

**Competition Has Played a Central Role in Part D's Success**

Competitive forces at work within Part D's structure have played a key role in achieving the program's favorable outcomes, including incentives for plans seeking to obtain enrollment in a consumer choice environment, negotiated drug prices, and beneficiary choice among plans. The result has been a strong record of affordability outlined above and, on average, broader

beneficiary access to medicines as compared to other public programs. For instance, Part D does not have arbitrary limits on the number of prescriptions covered per month, a feature that can be found in a number of state Medicaid programs. Additionally, as discussed further below, Part D plans generally have broader choice of medicines than is available in the Department of Veterans' Affairs (VA) drug benefit.

Many outside observers have also recognized the positive impact of competition within Part D. Former CBO Director Peter Orszag said, “[T]he bids are coming in and pricing is coming in better than anticipated, and that is likely a reflection of the competition that's occurring in the private market.”<sup>57</sup> In announcing a Part D premium decrease for 2012, former Acting CMS Administrator Dr. Donald Berwick stated that “a competitive market and good competition among Part D plans” have played a critical role in controlling program costs.<sup>58</sup>

The competitive features of the Part D market clearly drive savings along with access. In fact, Part D plans provide more robust access than in programs like the VA or that would be provided under alternative approaches. CMS’ standards set under the legislation creating Part D play a role in striking a balance between access and affordability, which will always be a dynamic issue within the program. CMS must remain diligent in monitoring the program to help sustain that balance.

*Negotiated Prices within Part D*

Robust negotiation of drug prices is one factor driving lower spending figures in Part D. Under current law and practice, private insurers and pharmacy benefit managers negotiate significant discounts and rebates on drugs dispensed to enrollees in their Part D plans and pass these savings on to beneficiaries and the Part D program. Evidence of such savings comes from the Government Accountability Office (GAO), which reported that Part D plans lowered costs for beneficiaries, “through their ability to negotiate prices with drug manufacturers and pharmacies … Sponsors must report the price concession amounts to CMS and pass price concessions onto beneficiaries and the program through lower cost sharing, lower drug prices, or lower premiums.”<sup>59</sup>

Some of Part D’s plan sponsors and their pharmacy benefit managers (PBMs) represent total patient populations of 40-50 million individuals, and also negotiate on behalf of private employers and the Federal Employee Health Benefit Program (FEHBP).<sup>60</sup> Just as in the commercial sector, these Part D plans negotiate to capture the largest possible discounts and rebates by using cost sharing and utilization management tools to steer patients to preferred medicines. CBO has found that Part D plans “have secured rebates somewhat larger than the average rebates observed in commercial health plans.”<sup>61</sup> The Medicare Trustees note that “many brand-name prescription drugs carry substantial rebates, often as much as 20-30 percent.”<sup>62</sup> Analysis of Medicare Trustee data shows that negotiated rebates have increased in each year of the program, repeatedly exceeding projected levels.<sup>63</sup>

Repeated increases in the reported average levels of negotiated rebates in Part D are a tangible example of competition at work. The statutory provisions concerning pass-through of these privately negotiated rebates, and the competition among part D plans to attract enrollees, translate into tangible savings for Medicare beneficiaries. CMS recently announced that for the 2014 plan year, “due to decreases in the cost of the Medicare prescription drug program,” the standard Part D prescription drug benefit will have lower co-payments and a lower deductible than in 2013.<sup>64</sup>

*Powerful Incentives for Cost Control Have Driven Rapid Take-up of Generics*

Some observers have suggested that most of Part D’s cost containment success is attributable to the “patent cliff” – an increase in generic use that happens when innovator medicines’ patents expire. These observers argue that the similarity between drug spending trends inside and outside of Part D suggest no particular benefit from competition in Part D. But this argument misses several key points.

First, the timing and scale of the patent cliff has been well-known for many years, yet the 10-year cost projections for Part D continue to decline sharply – as previously mentioned, by over \$100 billion in each of the past three years.<sup>65</sup>

Second, Part D was expressly designed to leverage the competitive tools already built into and widely used in the commercial marketplace, with plans and PBMs operating in a national market and highly sophisticated at purchasing drugs using plan design and formulary tools to negotiate discounts and rebates from brand manufacturers and drive high generic use rates among beneficiaries. Thus, Part D trends that are broadly similar to those in the commercial market reflect the competitive forces in the commercial sector and built into the Part D model.

Third, as discussed above, generics are a part of the competitive landscape in the U.S. market, representing a stage of the prescription medicine lifecycle. The U.S. market maximizes savings from use of generics, which is possible only because that drug was developed through the work and investment of an innovator company. Generic drugs now account for 84% of all prescriptions filled in the U.S.,<sup>66</sup> a higher rate than in many other developed countries. Additionally, while the competitive U.S. market operates to maximize savings from generics the 30 most commonly prescribed generic drugs are, on average, priced 96% higher outside the U.S.<sup>67</sup> High rates of generic use are an inherent characteristic of the competitive market that achieves savings while allowing reallocation of resources to medical advances, not a separate, independent force.

According to data from IMS Health, the share of generic drugs dispensed in Part D has grown by 20 percentage points since the beginning of the program. Generic use in Part D is expected to continue to grow in future years.<sup>68</sup>

Reflecting the prescription drug lifecycle that starts with innovation, a study conducted by IMS Health and a leading economist at the Massachusetts Institute of Technology, and supported by PhRMA, reported that the average daily cost of therapy for the ten most used therapeutic classes at the start of Part D declined by a third between 2006 and 2010, from \$1.50 to \$1.00; the average daily cost of therapy is projected to drop further to \$0.65 by the end of 2015.<sup>69</sup>

*Choice of Plans Promotes Competition and Cost Savings*

Part D provides beneficiaries choice among plans, which promotes plan competition for enrollment and allows beneficiaries to select a plan that meets their individual cost and coverage needs. Some have questioned whether beneficiaries can make good choices among plans. Although there will always be opportunities to improve the match between a beneficiary's needs and the plan they choose, there are strong indications that beneficiaries have done a good job at navigating the choices available to them.

At the program's inception, a study commissioned by PhRMA found that in both 2006 and 2007 a very large majority of beneficiaries chose plans that combined lower-than-average premiums, and a broad choice of medicines.<sup>70</sup> More recently, MedPAC reported that over 13% of Part D enrollees switched plans in 2010 and 2011, more than double the rate reported at the outset of the program.<sup>71</sup> Other new research finds that Part D enrollees who switched plans reduced their average annual out-of-pocket costs by almost \$300,<sup>72</sup> with researchers noting, “[o]ur results add to the accumulating evidence that Part D represents a successful implementation of a market-based approach to deliver a large-scale entitlement program.”<sup>73</sup>

**Effective Negotiation Takes Place Today in Part D**

There is a widely held misperception that Part D bars negotiation of drug prices. That view is wrong. As already discussed, robust negotiation by large, powerful purchasers with many tools at their disposal and incentives to achieve savings is at the heart of Part D.

Claims that Part D prohibits negotiation misread the law's “noninterference” clause.<sup>74</sup> This language, which had origins in the Clinton Administration's Medicare prescription drug proposal and was later adopted in the legislative proposals advanced by both Democrats and Republicans before Part D was enacted, clearly provides *for* negotiation rather than barring negotiation. In fact, its express purpose is “to promote competition under [Part D].”<sup>75</sup> However, the noninterference clause prohibits the *government* from “interfering” in the negotiations among Part D sponsors, pharmacies, and drug manufacturers, and from establishing a particular formulary for the program. Thus, with explicit safeguards in the law to protect negotiations, it is clear that active negotiations were at the heart of Part D's design. The real question about “negotiation” is not whether it should happen but *who* should negotiate.

Private plans and their PBMs negotiate price concessions with manufacturers and set formularies according to standards enforced by CMS (these standards allow for a range of outcomes rather

than forcing uniformity in benefits and formularies). These sponsors and PBMs have long experience and deep expertise in negotiating with manufacturers and they bring to negotiations the purchasing clout of total patient populations of 40-50 million individuals. They also have the incentives and tools to drive hard bargains, and the expertise and infrastructure needed to purchase medicines and ensure the benefit includes appropriate medicines, including Pharmacy and Therapeutics (P&T) committees and other clinical experts.

The government does not match the experience, expertise, clinical knowledge and infrastructure that an ExpressScripts or UnitedHealthcare brings to the negotiating table,<sup>76</sup> because these private purchasers participating in Medicare also purchase medicines on behalf of tens of millions of consumers in the other parts of the health care marketplace, such as employer-sponsored insurance or FEHBP. Further, these private purchasers negotiate in a competitive market that gives Part D beneficiaries choices to align their needs with a plan. Those who suggest that the Secretary of Health and Human Services would be better positioned to negotiate on behalf of all Medicare beneficiaries don't account for these many other important factors that are foundational to the design of the Part D benefit.

For Secretarial negotiation to achieve larger savings than those achieved by Part D plans (with their strong record of cost containment), the Secretary would be expected to restrict access to medicines more than in today's program. The non-partisan CBO has consistently stated<sup>77</sup> that striking noninterference "would have a negligible effect on federal spending because ... the Secretary would be unable to negotiate prices across the broad range of covered Part D drugs that are more favorable than those obtained by Part D plans under current law." To negotiate prices lower than those already achieved through negotiation between Part D plans and manufacturers, CBO states the government would need to impose additional access or coverage restrictions on Part D medicines, noting, "...the negotiating lever that's used to lower drug prices is the threat of not allowing that drug to be prescribed or putting limitations on its being prescribed within that drug plan."<sup>78</sup> Thus, the most likely outcome would be a one-size-fits-all formulary and benefit structure, since the Secretary would presumably be negotiating on behalf of all Medicare beneficiaries and negotiation typically is centered on formulary placement and tiering. It is difficult to imagine that the Secretary could or would negotiate for the unique characteristics of each plan and formulary, or that the Secretary could appropriately engage in such commercially sensitive decisions for plans that compete with one another and that are regulated by the Secretary.

#### **VA Model Would Not be Sustainable for Medicare**

Some critics of the Part D program argue that drug prices should be "negotiated" for Part D as they are for the VA drug benefit. But proposals to use the VA as a model for Part D do not account for how the VA system works, and as a result underestimate the impact that would come from such a sweeping change. First, the VA prices are based on a statutory government price control formula. As discussed below, government price controls would damage the

biopharmaceutical research enterprise that patients and policymakers alike count on to produce medical advances.

Second, VA operates a single national formulary with a limited range of available medicines, rather than giving veterans a choice among plan formularies as is the case in Part D. Moreover, this single VA formulary provides much more restrictive access to medicines than is typical in Part D. In a 2011 analysis by the Lewin Group for PhRMA, the most popular Part D plans covered 93% of the most routinely prescribed drugs for seniors, but only 67% of these drugs were covered by the VA formulary.<sup>79</sup> Notably, a VA sponsored survey reports that about 40% of veterans supplement their VA coverage with Part D or private insurance,<sup>80</sup> documenting that when VA beneficiaries have a choice, a majority prefer not to be limited to just the VA benefit.

Further, the VA delivers care through a closed health system, while Medicare beneficiaries rely on community physicians. When VA experimented with allowing veterans to use community physicians, up to 42% of all prescriptions prescribed were for medicines not on the VA formulary. Even after VA spent 20 weeks working to switch these prescriptions to on-formulary medicines, an average of 27% remained off formulary.<sup>81</sup> In sum, imposing the VA system on tens of millions of Medicare beneficiaries, most of whom would not have the option of another prescription drug plan, would have broad implications for access to care. For these reasons, the share of VA enrollees who plan to use VA services primarily for prescriptions in the future is steadily declining, and fell from 17% in 2005 to 8% in 2011.<sup>82</sup>

Finally, VA covers a relatively small population and as discussed above frequently does not serve as its enrollees' sole source of prescription drug coverage. Part D's enrollment is more than three times larger, and as a Yale economist has indicated,<sup>83</sup> low pricing levels sustained via price controls for smaller programs cannot be expected to produce the same prices in Medicare. A restrictive, closed system designed for a very specific, small population does not translate easily to the diverse needs of over 35 million seniors and disabled beneficiaries.

**Applying Medicaid's Price Controls to Part D Would Not Return to a Prior Status Quo and Would Disrupt the Competitive Dynamics Responsible for the Program's Success**

Some policymakers have called for applying Medicaid price controls to medicines dispensed to recipients of the LIS in Medicare Part D. This policy would represent the first time that Medicaid payment rates would be mandated for the provision of Medicare services, establishing a different payment rate for a Medicare service based on a beneficiary's income level.

Policymakers advocating for this new policy often base their position on the fact that dual eligibles obtained their prescription drug coverage through Medicaid prior to implementation of Part D in 2006. Essentially, they argue that imposing Medicaid's price controls in Medicare would be a return to the pre-Part D status quo. However, this does not accurately describe the proposal or its likely impact.

First, prescription drug coverage for approximately six million dual eligible beneficiaries was intentionally transferred from Medicaid to Medicare by the MMA, a move that had the strong support of beneficiary advocates.<sup>84</sup> At the same time, nearly twice that number (11 million) of individuals gained comprehensive drug coverage through Part D.<sup>85</sup> By gaining coverage, these individuals went from purchasing medicines at retail prices to benefiting from discounts and rebates from manufacturers that are negotiated by large, powerful purchasers. Part D also strengthened the negotiating power of payers by greatly increasing the number of covered lives, introduced the specialty tier that is now common in the insurance marketplace, and likely increased generic use beyond what it otherwise would have been. CMS reported in Part D's first year that many Part D plans increased generic use faster than the market as a whole.<sup>86</sup> In sum, at its inception, Part D had many moving parts; focusing on one to the exclusion of all others is not a good basis for judging impact or making policy.

Second, these proposals would extend Medicaid price controls far beyond the population ever eligible for Medicaid benefits by applying to drugs dispensed to millions of additional Medicare beneficiaries who receive the Part D LIS but who are not and never were eligible for Medicaid drug benefits. The most recent Medicare Trustees report estimated that in 2012, Part D would have about 6.9 million dual eligibles, and 4.2 million non-dual eligible LIS enrollees.<sup>87</sup> Thus, this policy would extend Medicaid price controls to a population of LIS recipients that is 160% of the size of the dual eligible population alone.

Third, both the Medicaid and Part D programs have gone through changes since 2006 that further distance today's proposals from the pre-Part D status quo. For example, in 2006, the statutorily required minimum rebate percentage on brand prescription drugs in Medicaid was 15.1 % of the drug's average manufacturer price (AMP). Subsequent legislation has raised the minimum mandatory rebate to 23.1 % of AMP, and this is the minimum rebate amount that is assumed in current proposals. Thus, current proposals would apply a much higher rebate percentage in Part D than ever applied to full-benefit dual eligibles when they previously received drug coverage under Medicaid. The effects of taking a Medicaid policy enacted in 2010 and imposing it on Medicare Part D today would not be a return to the status quo of 2006.

Moreover, current rebate proposals do not account for the tens of billions of dollars in new discounts and fees that brand manufacturers pay. For example, biopharmaceutical manufacturers are now required to pay a 50% discount on all brand drugs dispensed to enrollees who are in the Part D coverage gap<sup>88</sup> and to pay new fees into the Medicare program.<sup>89</sup> Furthermore, Medicaid price controls for prescription medicines were extended to tens of millions of additional individuals in Medicaid managed care. Altogether, analysts estimate the biopharmaceutical sector will pay more than \$100 billion over ten years through provisions of the Affordable Care Act.<sup>90</sup> These policies were not in place in 2003 when the MMA was signed into law or in 2006 when Part D was implemented, making any claim that imposing price controls is a return to the pre-Part D status quo incorrect.

To summarize, current proposals fail to account for both the many changes made by the MMA creating Part D and significant statutory changes in Medicaid and Part D since 2006, and would greatly expand the reach of Medicaid price controls to individuals who are not eligible for Medicaid benefits. There is not a justification for imposing Medicaid price controls on a Part D program that has achieved a strong record of cost containment, beneficiary satisfaction, and improved health outcomes.

*Adverse Impact of Medicaid Price Controls on Part D and Beneficiaries*

Part D's competitive structure already includes substantial negotiated discounts and rebates, and Part D plans have strong incentives within the current framework to reduce costs and appropriately manage drug spending. Layering market-distorting government price controls on top of a program that was designed to operate – and successfully does so – on a model employing negotiated discounts would not be a small or modest adjustment. Rather, it would undermine the program's balance of competitive forces and effectively shift to a reliance on traditional government-imposed line item price controls, despite the strong successes achieved for beneficiaries and taxpayers by the program's competitive structure.

Unlike the market-based rebates currently negotiated and passed through to beneficiaries in the form of lower premiums, deductibles, and cost sharing, mandatory government rebates in Part D would not return savings to Medicare beneficiaries. CBO has recognized that legislation imposing this type of price control in Medicare Part D could contribute to an increase in beneficiary premiums.<sup>91</sup> Additionally, a former CBO director, as well as a Chief Actuary of CMS and a former senior CBO analyst have jointly cautioned that imposing Medicaid rebates in Part D would undermine the competitive dynamics in Part D and lead to significant market distortions, potentially leading to higher premiums, reduced choices, higher copays, and more restrictive formularies.<sup>92</sup>

In a larger sense, requiring Medicaid-style rebates on drugs dispensed to Part D LIS beneficiaries would apply different pricing rules to low-income Medicare beneficiaries, since millions of Medicare beneficiaries in Parts A and B are either full-benefit dual eligibles or are receiving assistance from Medicaid in paying Medicare Part A or B cost-sharing or premiums. If Medicaid pricing became an accepted benchmark for Medicare, is unclear whether current Medicare benefits could be sustained.

**Preserving Incentives for R&D and Continued Medical Progress**

Proposals for new price controls in Part D could have a negative impact on R&D investment in the U.S. Today, the U.S. leads the world in drug discovery and development, and the potential for scientific breakthroughs in multiple disease areas has never been greater.

CBO has reported that a Medicaid-style rebate in Part D would reduce incentives for innovation “on products that would be expected to have significant Medicare sales”<sup>93</sup> and numerous reports by government agencies and academics have found that government price controls would harm future innovation and access to medicines.<sup>94</sup> For example, RAND researchers modeling the impact of price controls in the U.S. find they would negatively impact R&D investment needed for the development of new medicines and ultimately, health care outcomes. They conclude that “price regulations represent a risky policy strategy that may have a modest impact on lowering health costs in the United States, while having a longer-term cost of reducing development of new drugs that can reduce suffering and prolong life.”<sup>95</sup>

Biopharma R&D can have a bright future as new scientific discoveries are opening up extraordinary possibilities for treating some of our most challenging and costly diseases. At the same time, it’s important to recognize that analysts are increasingly citing falling returns on R&D in recent years, which may impact the industry’s ability to bring these new medicines out of the pipeline. Notably, McKinsey & Company notes, “The return on investment for a typical biopharmaceutical portfolio today often will not even cover its cost of capital.”<sup>96</sup> Indicative of such challenges venture capital (VC) investment in emerging biopharmaceutical companies has been declining in recent years,<sup>97</sup> and continues to be under severe pressure due to the escalating time, increased costs and uncertainty of new product development, combined with increasing coverage and payment pressures.<sup>98</sup> New government price controls in Medicare would likely tip the scales resulting in further VC investment declines in the biopharma sector to less risky sectors.<sup>99</sup>

The biopharma sector is working hard to evolve in this new century to achieve new efficiencies and harness the full potential of the scientific and technological advancements now available to us, so that the R&D process can be more productive. Likewise, the policies that govern how we work and how the health system works need to evolve. Part D was a part of that evolution in policy; applying government price controls would move backward. Only by evolving policy and science together will we achieve the biomedical advances that patients are counting on.

#### **Potential Areas for Improvement in Part D**

While the Part D program has been highly successful, there are opportunities to improve the program and ensure that all beneficiaries are receiving high quality care. One important opportunity for improvement relates to the Medication Therapy Management (MTM) Program, which was intended to optimize medication use among Part D beneficiaries. A recent CMS report evaluating the impact of MTM for beneficiaries with two costly chronic conditions, congestive heart failure and chronic obstructive pulmonary disease, found that the program was successful in increasing adherence and lowering hospitalization costs.<sup>100</sup> These findings are consistent with the research discussed above, showing that appropriate prescribing of medication therapy and better adherence improve quality and outcomes, while often reducing total costs and use of other more expensive health services.<sup>101</sup>

Given MTM's potential to both improve outcomes and lower costs, it is important that the program reach the full range of beneficiaries who would benefit from active medication management. Part D plan sponsors tend to interpret the minimum eligibility criteria outlined by CMS in a way that misses many chronically ill beneficiaries who are at risk for underuse of medicines or poor adherence. CMS should consider specifying additional MTM eligibility criteria beyond drug costs, such as medication classes that treat chronic conditions, targeting beneficiaries that have high overall health spending rather than just high drug spending (which may require a waiver from the statutory eligibility provisions), or lowering the minimum Part D drug count threshold. We also encourage CMS to make its MTM data available to researchers, in order to determine which MTM program elements are most effective and to investigate ways to increase beneficiary participation in the program.

The MTM program also provides an opportunity to identify potential overuse, misuse or abuse within Part D and should be integrated with other efforts to identify problematic patterns of utilization, including drug-drug interactions, contraindicated medications, and medication errors. To further aid in identifying potential problems, we support CMS proposals to facilitate sharing of beneficiary-level utilization management data when beneficiaries change plans. Such data sharing could help plans identify potential safety risks and address plan shopping and doctor shopping that is driven by fraud and prescription abuse. It could also help avoid instances in which beneficiaries are required by a new plan sponsor to repeat a prior authorization process or step therapy program undergone previously, as this extra step can unnecessarily deny access to needed treatments. Separately, CMS could build on the Electronic Health Record (EHR) incentive program to encourage participating physicians to complete annual medication reviews for their patients, and work to assure that EHRs incorporate medication fill data from PBMs and health plans.

Assuring that beneficiaries are able to make well-informed choices among plans is key to the success of Part D. As discussed earlier, MedPAC has recently reported that a larger share of beneficiaries are switching plans during annual open enrollment, and other research shows that switchers save money. There may be further opportunities to provide information to beneficiaries that would encourage them to shop when appropriate and help in identifying plans that would provide the best mix of access, premiums, and out of pocket costs.

Finally, improvements could be considered to ensure that the use of a specialty tier in Part D does not undermine access to needed medicines. In our past comments to CMS, we have recommended a more patient-centered approach that would allow patients to appeal specialty tier cost sharing by demonstrating a medical need for the specialty tier drug, as the rules allow for medicines on other tiers. CMS should also assure that a therapeutic alternative in the class be available to patients in a preferred tier before a medicine may be placed in the specialty tier.

Taking these steps would ensure that patients needing specialty medicines do not face high barriers to accessing care.

#### **Conclusion**

I thank the Committee for convening this hearing to assess what we have learned in the 10 years since the Part D program was enacted. As I see it, a number of lessons have emerged.

First, the combination of private sector competition under government oversight of beneficiary protections has worked. The robust participation of plan sponsors and beneficiaries, combined with the continued reduction of Part D spending estimates and high enrollee satisfaction ratings all testify to this. Like any program, Part D could benefit from small adjustments and improvements; but on balance, the program has been high performing.

Second, beneficiaries value choice and have been able to make good decisions to address their cost and individual coverage needs. While some may need extra guidance and support to access what they need, Medicare beneficiaries are using the tools available to them to choose plans that work for them. It is not likely that a single plan could meet beneficiaries' varied needs as successfully as many plan offerings do.

Third, better use of medicines has a strong track record of improving health and generating cost savings in other parts of Medicare by reducing hospitalizations and emergency department visits. Even with the improvements in utilization patterns brought about by Part D, there is much room for continued improvement. This is a rare opportunity in health care.

Fourth, Part D includes many effective cost containment features and incentives to provide good access to medicines. Government price controls and Secretarial "negotiation" are directly at odds with this system; injecting them would be a step backward that would undermine foundational aspects of the program.

Finally, we need to support continued biopharmaceutical innovation. Innovation is central to achieving widely agreed upon goals such as continuing to change the course of cancer, mental illnesses and neurodegenerative diseases, just as we've changed the course of HIV, hepatitis C and heart disease. Innovation can also support a more affordable health care system; as our society ages, Alzheimer's alone will cost Medicare and Medicaid close to \$300 billion annually by 2030 without new medicines that delay its onset or slow its progression. Many biopharma research companies have been working at this, and there have been many highly publicized instances in which promising drugs that have been brought through the clinical trials have not achieved their goals and their development had to be cancelled. Companies continue to work on potential new treatments, just as they worked through scores of failures before developing the first approved medicine that cuts off the blood supply that cancer tumors use to grow.

With the right policy framework underpinning the innovative biopharma research enterprise, it will continue to make the future better than the past, with scientific advances yielding remarkable progress against disease along with economic growth and hope for patients.

Thank you for allowing me to testify today. I am happy to answer any questions you may have.

<sup>1</sup> CBO, "Research and Development in the Pharmaceutical Industry," October 2006.

<sup>2</sup> PhRMA analysis of National Science Board, "Science and Engineering Indicators," National Science Foundation, 2012.

<sup>3</sup> PhRMA Industry Profiles, 2001-2013.

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<sup>43</sup> Calculation based on MedPAC data in, "Report to the Congress: Medicare Payment Policy," March 2013, p. 342.

<sup>44</sup> See CBO Medicare Baselines available at [www.cbo.gov](http://www.cbo.gov)

<sup>45</sup> CMS, Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter , p. 43, Table III-1. Note: 2013 datum is a projection.

<sup>46</sup> See CBO Medicare Baselines for 2004, 2010, and 2013, Components of Mandatory Outlays, available at [www.cbo.gov](http://www.cbo.gov)

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<sup>48</sup> See CBO Medicare Baseline, February 2013.

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<sup>58</sup> Nocera, "Medicare prescription drug costs to go down," POLITICO, August 4, 2011, <http://www.politico.com/news/stories/0811/60689.html>

<sup>59</sup> Source: "Overview of Approaches to Control Prescription Drug Spending in Federal Programs." Statement of John E. Dicken Director, Health Care, Government Accountability Office, before the Subcommittee on Federal Workforce, Postal Service, and

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the District of Columbia, Committee on Oversight and Government Reform, House of Representatives, June 24, 2009. <http://www.gao.gov/new.items/d09819t.pdf>

<sup>60</sup> AIS's Pharmacy Benefit Survey Results: 3rd Quarter 2012

<sup>61</sup> March 12, 2007 CBO letter to the Honorable Joe Barton and the Honorable Jim McCrery, page 3.

<sup>62</sup> See 2012 Medicare Trustees Report, p. 166, footnote 72.

<sup>63</sup> 2012 Medicare Trustees Report, p. 166, Table IV.B9; and Medicare Trustees Reports for 2007, 2008, 2009, 2010, and 2011.

<sup>64</sup> CMS Press Release, "CMS Proposes 2014 Payment and Policy Updates for Medicare Health and Drug Plans" February 15, 2013. [www.cms.gov](http://www.cms.gov)

<sup>65</sup> See CBO Baselines for 2010 to 2013, available at [www.cbo.gov](http://www.cbo.gov).

<sup>66</sup> IMS Health. *National Prescription Audit Custom Run*. 2012.

<sup>67</sup> Squires DA. *Explaining High Health Care Spending in the United States: An International Comparison of Supply, Utilization, Prices, and Quality*. The Commonwealth Fund; 2012.

<sup>68</sup> IMS Institute for Healthcare Informatics, "Declining Medicine Use and Costs: For Better or Worse? A Review of the Use of Medicines in the United States in 2012," May 2013.

<sup>69</sup> IMS Institute for Healthcare Informatics, "Medicare Part D at Age Five: What Has Happened to Seniors' Prescription Drug Prices?" July 2011.

<sup>70</sup> Analysis for PhRMA by The Lewin Group, August 2007. Based on data collected from the Medicare Plan Finder and CMS plan-level enrollment data released July 2007.

<sup>71</sup> MedPAC, "Report to the Congress: Medicare Payment Policy," March 2013, p. 359.

<sup>72</sup> Ketcham, JD et al. "Sinking, Swimming, or Learning to Swim in Medicare Part D" *American Economic Review*, 2012, 102(6): 1-38.

<sup>73</sup> *Ibid*, p. 31

<sup>74</sup> See Social Security Act, Section 1860D-11(i)

<sup>75</sup> *Ibid*.

<sup>76</sup> This raises the question of how the Secretary would even operationalize negotiation. As CBO points out, negotiation typically centers on the terms under which a medicine will be covered by a plan. Thus, the Secretary would have to make tiering and utilization management decisions for each drug about which she negotiates and then fit that into each plan. But plans differ, some may already have negotiated satisfactory terms for coverage of a particular drug or one of its competitors, and the Secretary's decision about tiering or utilization management rules may undermine those decisions, or be inconsistent with those plans benefit design. This is just one question about "negotiation" by the Secretary and suggests that allowing interference by the Secretary in existing negotiations between plans and manufacturers would profoundly change the character of Part D in a way that moves away from choice, competition and access.

<sup>77</sup> CBO Letter to the Hon. Bill Frist, January 23, 2004.

<sup>78</sup> Remarks of CBO Director Dr. Douglas Elmendorf before the Senate Finance Committee, February 25, 2009

<sup>79</sup> The Lewin Group; 2011 Comparison of VA National Formulary and Formularies of the Highest Enrollment Plans in Medicare Part D and the Federal Employee Health Benefit Program, February 16, 2011.

<sup>80</sup> "2011 Survey of Veteran Enrollees' Health and Reliance Upon VA," Department of Veterans Affairs, March 2012, pp. A-1 and A-18.

<sup>81</sup> Statement of Dr. Jonathan Perlin, Deputy Under Secretary for Health Department of Veterans Affairs; March 30, 2004 (Found at <http://www.va.gov/OC/A/testimony/hvac/sh/040330JP.asp>)

<sup>82</sup> "2011 Survey of Veteran Enrollees' Health and Reliance Upon VA," Department of Veterans Affairs, March 2012, p. 57.

<sup>83</sup> Fiona Scott Morton, Testimony before the House Oversight and Government Reform Committee, "Medicaid Rebates, the Economics of the Pharmaceutical Industry, and the Medicare Part D Program," 24 July 2008.

<sup>84</sup> See "The Six Million Medicare Beneficiaries Excluded From Prescription Drug Benefits Under the Senate Bill are Disproportionately Minority," Leighton Ku and Matthew Broadus, Center on Budget and Policy Priorities, September 9, 2003; AARP News Release, "Letter by AARP CEO Bill Novelli to Congress Concerning Prescription Drug Benefit in Medicare," July 14, 2003; Center for Medicare Advocacy, "A Baker's Dozen of Reasons Why It's a Bad Idea to Make Dual Eligibles Get Their Drug Benefit Through Medicaid."

[http://medicareadvocacy.org/InfoByTopic/PartDandPrescDrugs/PrescDrugs\\_13ReasonsAgainstUsingMedicaid.htm](http://medicareadvocacy.org/InfoByTopic/PartDandPrescDrugs/PrescDrugs_13ReasonsAgainstUsingMedicaid.htm), accessed April 17, 2013.

<sup>85</sup> C. Afendulis and M. Chernew, "State-Level Impacts of Medicare Part D," *American Journal of Managed Care*, October 2011.

<sup>86</sup> Statement of Dr. Mark B. McClellan, CMS Administrator; September 21, 2006 (Found at: <http://www.hhs.gov/asl/testify/t060921.html>).

<sup>87</sup> See 2012 Medicare Trustees Report, p. 164, Table IV.B8.

<sup>88</sup> Section 3301 of the Patient Protection and Affordable Care Act (PL 111-148), as amended by Section 1101 of the Health Care Education and Reconciliation Act (PL 111-152).

<sup>89</sup> *Ibid*.

<sup>90</sup> PricewaterhouseCoopers, "Implications of the US Supreme Court ruling on Healthcare," June 2012, p. 6.

<sup>91</sup> CBO, Budget Options Volume I Health Care, March 2008, p. 125; Letter from Douglas W. Elmendorf, CBO Director, to Rep. Dave Camp 3 (Aug. 28, 2009), available at <http://www.cbo.gov/ftpdocs/105xx/doc10543/08-28-MedicarePartD.pdf>.

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<sup>92</sup> Antos & King, "Tampering with Part D Will Not Solve Our Debt Crisis," American Enterprise Institute Health Studies Working Paper, June 2011.

<sup>93</sup> CBO, "Pharmaceutical R&D and the Evolving Market for Prescription Drugs" October 26, 2009, p. 7. <http://www.cbo.gov/ftpdocs/106xx/doc10681/10-26-DrugR&D-sds10-26.pdf>

<sup>94</sup> See J. Vernon, Examining the Link Between Price Regulations, Reimportation, and Pharmaceutical R&D Investment, AEI-Brookings Joint Center for Regulatory Studies Publication 04-06 (Washington, DC: AEI-Brookings Joint Center for Regulatory Studies, April 2004); B. Zycher, "The Human Cost of Drug Price Negotiations," RealClearPolitics, Nov. 29, 2006; Pugh, T. Medicare Drug plan may hit snag in Senate." Miami Herald, Jan. 8, 2007 (<http://www.miami.com/mltd/miamiherald/16407138.htm>); D. Lackdawalla and D. Goldman, et al, "U.S. Pharmaceutical Policy in a Global Marketplace," Health Affairs, Web Exclusive, December 16, 2008; N. Sood and H. de Vries, et al. "The Effect of Regulation On Pharmaceutical Revenues: Experience in Nineteen Countries," Health Affairs, Web Exclusive, December 16, 2008; F.M Scherer "Pharmaceutical Innovation," Working Paper 07-13 AEI-Brookings Joint Center for Regulatory Studies, June 2007; Congressional Budget Office, Research and Development in the Pharmaceutical Industry, (Washington, DC: CBO, October 2006), See U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Securing the Benefits of Medical Innovation for Seniors: The Role of Prescription Drugs and Drug Coverage (July 2002), available at <http://aspe.hhs.gov/health/Reports/medicinalinnovation/innovation.pdf>; Implications for U.S. Consumers, Pricing, Research and Development, and Innovation, 30-31 (Dec. 2004); U.S. Department of Health and Human Services Task Force on Drug Importation, Report on Prescription Drug Importation (Dec. 2004); Government Accountability Office, New Drug Development: Science, Business, Regulatory and Intellectual Property Issues Cited as Hampering Drug Development Efforts 6 (Nov. 2006); Giancotto, Santerre & Vernon.

<sup>95</sup> BNA's Health Care Daily, "Rx Drug Price Regulations Would Stifle Future Medical Innovation, RAND Studies Say," December 17, 2008

<sup>96</sup> Eric David et al. "New frontiers in pharma R&D investment," McKinsey Quarterly, February 2010.

<sup>97</sup> PricewaterhouseCoopers & National Venture Capital Association, "2012 Money Tree Report," January 2013.

<sup>98</sup> National Venture Capital Association. Patient Capital 3.0. Confronting the Crisis and Achieving the Promise of Venture-Backed Medical Innovation. NVCA, April 2013.

<sup>99</sup> *Ibid.*

<sup>100</sup> G.M. Marrufo et al. Medication Therapy Management in a Chronically Ill Population. January 2013. Available at: <http://innovation.cms.gov/Files/reports/MTM-Interim-Report-01-2013.pdf>

<sup>101</sup> Examples include, but are not limited to: W.H. Shrank, et al. "A Blueprint for Pharmacy Benefit Managers to Increase Value," *American Journal of Managed Care*, February, 2009.; D. Cutler, et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," *Health Affairs*, January/February 2007.; M. Cloutier, et al., "Asthma Guideline Use by Pediatricians in Private Practices and Asthma Morbidity," *Pediatrics*, November 2006.; M. Sokol et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, June 2005.

The CHAIRMAN. Thank you, Mr. Smith, and congratulations on your industry developing extraordinarily wondrous new drugs. And this will continue.

Mr. SMITH. Thank you, sir.

The CHAIRMAN. Mr. Romasco.

#### **STATEMENT OF ROBERT G. ROMASCO, PRESIDENT, AARP**

Mr. ROMASCO. Chairman Nelson, Ranking Member Collins, Senator Warren, my name is Rob Romasco. I am a member of AARP's all-volunteer board of directors, and I proudly serve as AARP's president.

On behalf of AARP's more than 37 million members, we thank you for holding this hearing on the Medicare Part D Prescription Drug Program.

As we approach the tenth anniversary of the Medicaid Modernization Act, Part D is helping millions of Medicare beneficiaries afford the prescription drugs they need.

AARP continues its strong support of the Medicare drug benefit, which provides help to older Americans, those with disabilities and those with low incomes or catastrophic drugs costs. Part D has improved their access to prescription drugs. Prescription drug coverage plays a vital role in the health and financial security of older Americans. Part D has been a true success in helping seniors get and stay healthy.

As part of the Affordable Care Act, the initial Part D coverage gap is slowly being eliminated through escalating discounts. According to CMS, these changes have helped save people more than \$5.1 billion on prescription drugs.

Chairman Nelson, I would like to take this opportunity to thank you for your support of this key provision of the ACA.

The Part D is coming under budget. We have heard the estimate is 30 percent lower than CBO's projection 2003. Last year, CBO acknowledged that taking medications helps prevent hospital admissions and reduces the use of other medical services. This shows the importance of Part D in helping control spending in the Medicare program and, critically, offers a path to controlling costs throughout the entire health care system.

Among the most important protections in Part D is the extra help provided by the low-income subsidy to help those least able to afford their drugs.

Amid the successes of Part D, however, we see opportunities for improving the program.

Our members, especially Medicare beneficiaries, still tell us they continue to struggle to afford prescriptions. The Asset Test is a particular concern. To be eligible for the low-income subsidy in 2013, beneficiaries cannot have \$1 more than \$13,300 in savings. This is hardly enough to get through the years of retirement, and that is why AARP has consistently opposed the Asset Test.

Also, AARP believes recent recommendations to modify prescription drug co-payments for low-income beneficiaries may be premature. Instead, we recommend further research to help understand what is driving utilization and to ensure that any changes in the LIS benefit will not interfere with access to necessary drugs.

Also, Part D enrollees are faced with increasing cost-sharing as the drug plans get more complex, with more cost-sharing tiers and increased cost-sharing for both preferred and nonpreferred brand name drugs.

Further, AARP does not support making Part D enrollees pay higher premiums based on their income. Seniors in Medicare have already paid into the system through payroll taxes, and those with higher incomes paid more over their lifetimes. In many cases, seniors with higher incomes are still working and continue to pay Medicare taxes often because they do not have the savings they need to retire.

AARP is concerned that those with higher incomes may simply choose not to participate in Part D, fundamentally changing the nature and quality of the program.

We do, however, recognize we must take steps to reduce costs. AARP urges Congress to enact legislation that will lower overall costs in Part D rather than simply cost-shifting to older Americans and asking them to pay more for their care.

In that vein, we strongly support the Medicare Drug Savings Act which would require prescription drug manufacturers to provide rebates for drugs provided to low-income beneficiaries dually eligible for Medicare and Medicaid. This would restore savings they received prior to the enactment of MMA. This legislation is estimated to save \$141 billion over the next 10 years.

AARP looks forward to working with all members of Congress to enact this sensible legislation to improve fiscal stability of Medicare while protecting beneficiaries.

We have also consistently supported legislation that would enable the Secretary of HHS to use the bargaining power of Medicare's 49 million beneficiaries to negotiate lower drug prices.

Further, we support reducing the market exclusivity period for biologic drugs from 12 to 7 years. This could save billions for beneficiaries, the Medicare program, for employers and for health care payers.

In conclusion, we should focus on efforts to hold down costs, not simply shift costs in the form of either higher premiums or co-payments for Medicare beneficiaries.

We look forward to working with members of Congress on both sides of the aisle to improve Part D and find ways to keep drug coverage affordable for people with Medicare.

Thank you very much.

[The prepared statement of Mr. Romasco follows:]



**TESTIMONY BEFORE THE SENATE SPECIAL  
COMMITTEE ON AGING**

**“10 Years Later: A Look at the Medicare  
Prescription Drug Program”**

**By Robert G. Romasco  
AARP President**

**May 22, 2013**

**Room 366  
Dirksen Senate Office Building  
WASHINGTON, DC**

For further information, contact:  
Ariel Gonzalez  
AARP Government Affairs  
(202) 434-3770

Chairman Nelson, Ranking Member Collins, distinguished members of the Committee, on behalf of AARP's more than 37 million members, we thank you for holding this hearing on the Medicare Part D prescription drug program, which is helping millions of Medicare beneficiaries afford the prescription drugs they need. My name is Rob Romasco and I serve as AARP President.

AARP is pleased that this Committee is examining the progress of the Part D prescription drug benefit program as we mark its tenth anniversary. AARP continues its strong support of the Medicare drug benefit, which provides help to older persons and persons with disabilities, particularly those with low-incomes, those with catastrophic drug costs and those who have no other source of drug coverage.

Millions of prescriptions are being filled every day, and we know from our members that they are saving money as a result of the Medicare prescription drug coverage. AARP continues to support this vital coverage, and we look forward to working with members of the committee to continue to improve the program to both save money and improve health outcomes.

#### **Improved Access to Prescription Drugs**

Prescription drug coverage plays a vital role in the health and financial security of the older population. For older adults, prescription drugs are critical in managing their chronic conditions, curing diseases, keeping them healthy and improving their quality of life. The Medicare Part D program has truly been a success story in expanding access to prescription drug coverage for seniors. In general, survey analysis shows that seniors are very satisfied with the plan choices offered, their access to brand name and generic prescription drugs, and the affordability of their drugs with Medicare Part D coverage.<sup>1</sup> Since its implementation in 2006, the share of seniors with access to significant prescription drug coverage has increased from 75 percent to about 90 percent.<sup>2</sup> This includes persons who receive coverage through employer-sponsored retiree plans, the Veterans Administration, and other sources.

As part of the Patient Protection and Affordable Care Act (ACA), the initial Part D coverage gap is slowly being eliminated through a series of escalating discounts. According to the Center for Medicare and Medicaid Services (CMS), these changes – as well as a one-time \$250 rebate for enrollees who hit the coverage gap in 2010 – have already saved Medicare Part D enrollees more than \$5.1 billion on prescription drugs.<sup>3</sup>

The Part D program has also come in under budget, with the most recent figures showing the program's actual spending is about 30 percent lower than initial projections made by the Congressional Budget Office (CBO) in 2003 during consideration of the Medicare Modernization Act (MMA). The program's success is in part due to the competition among

<sup>1</sup> T. Keenan, *Prescription Drugs and Medicare Part D: A Report on Access, Satisfaction, and Cost*, AARP Knowledge Management, November 2007, [http://www.aarp.org/health/drugs-supplements/info-2007/fx\\_medicare\\_d.html](http://www.aarp.org/health/drugs-supplements/info-2007/fx_medicare_d.html). MedPAC analysis of 2010 Medicare Current Beneficiary Survey Access to Care file, March 2013.

<sup>2</sup> MedPAC, *Report to Congress: Medicare Payment Policy*, Chapter 15, Status report on Part D, March 2013.

<sup>3</sup> CMS, "People with Medicare save \$5 billion on prescription drugs thanks to the health care law," Press Release, December 3, 2012, [http://www.cms.hhs.gov/apps/media/press\\_releases.asp](http://www.cms.hhs.gov/apps/media/press_releases.asp).

multiple Part D plans. Consumers have the ability to choose between different options based on a range of criteria that meet their needs – such as premiums and cost-sharing, formularies, quality of services, and network adequacy – in order to make informed decisions about their prescription drug coverage. At the same time, several other factors have contributed to the Part D program's lower costs, including lower than projected enrollment, overall slower growth in prescription drug spending, increased use of generic drugs, expiration of many brand name drug patents since 2006, and fewer new drugs being approved by the Food and Drug Administration (FDA).<sup>4</sup>

Last year, new analysis by the CBO underscores the importance of prescription drug adherence on overall medical costs. CBO acknowledged for the first time the connection between taking medications and preventing hospital admissions and reducing the use of other medical services. In its review of the research, CBO found evidence of an offsetting effect of prescription drug use on spending for medical services. It now estimates that a 1 percent increase in the number of prescriptions filled by beneficiaries would cause Medicare's spending on medical services to fall by roughly one-fifth of 1 percent.<sup>5</sup> This new analysis shows the importance of the Part D program in helping to control spending elsewhere in the Medicare program.

#### **AARP's Educational Efforts**

Since the passage of the MMA, AARP has worked to provide information to our members and their families, as well as all Americans, about the changes to the Medicare program. AARP has produced numerous beneficiary-oriented publications explaining the Medicare Part D program. These publications are made available to our members and the public via the AARP website and our toll-free number. In addition, we have reached out to our members and the public at large with the information on the program through AARP's publications and the media. Our state and national offices conducted extensive education and outreach during implementation and in the run up to the initial enrollment deadline in 2006. We have particularly focused on outreach and education to low-income populations and encouraging those who may qualify to apply for the low-income assistance.

AARP and other consumer groups worked collaboratively with CMS and the Social Security Administration (SSA) to identify start-up problems in connection the program's implementation. Due to this important collaboration between government and stakeholders many of the initial problems and barriers to enrollment were addressed. However, the need for continued outreach and education on Part D remains as important as ever to ensure that seniors understand their options and receive appropriate drug coverage. According to a 2012 Kaiser Family Foundation National Survey, while the great majority of seniors (73 percent) say they are aware of the annual enrollment period and 60 percent say they

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<sup>4</sup> J. Hoadley, *Medicare Part D Spending Trends: Understanding Key Drivers and the Role of Competition*, Kaiser Family Foundation Medicare Policy Issue Brief, May 2012.

<sup>5</sup> Congressional Budget Office, "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services," November 29, 2012, <http://www.cbo.gov/publication/43741>.

compare their Medicare options as recommended, one in four seniors do not review their option routinely.<sup>6</sup>

Furthermore, despite CMS' commendable efforts to reduce the number of Part D plans that are available to enrollees, there is growing evidence that enrollees are still struggling to choose the best prescription drug plan to fit their needs. For example, research suggests that less than 10 percent of individuals enroll in plans that are optimal with respect to premiums and co-payments.<sup>7</sup> These choices can have serious financial implications: one study found that Part D enrollees spent an average of \$368 more per year than they would have spent had they purchased the cheapest plan available in their region, given their medication needs, and more than one-fifth spent at least \$500 a year more than needed.<sup>8</sup>

Continued outreach and education is critical so that seniors understand changes in their coverage and compare it with alternative options that might be more suited to their current medical needs or have lower out-of-pocket costs. AARP has also been actively involved in efforts with CMS to improve the Medicare Plan Finder. Refinements to the Medicare Plan Finder are needed to make it more user-friendly so that it can better assist Medicare beneficiaries as they analyze plan offerings to make informed decisions on selecting a plan.

#### **Current Snapshot of the Medicare Part D Program**

Medicare's outpatient prescription drug benefit, Part D, is a voluntary program available since 2006. Approximately 65 percent of Medicare beneficiaries participate. The standard Medicare Part D benefit consists of a deductible; an initial coverage period, in which enrollees are responsible for 25 percent of their prescription drug costs; a coverage gap, in which enrollees are responsible for a large, but declining part (due to the ACA provision that took effect in 2011) of their prescription drug costs; and catastrophic coverage, in which enrollees are responsible for 5 percent of their prescription drug costs. Enrollees who receive Part D's low-income subsidy (LIS) have very low and uniform cost-sharing throughout the year and do not face a coverage gap.

In 2013, enrollees fall into the coverage gap after their total prescription drug spending reaches \$2,970 and enter catastrophic coverage after their total out-of-pocket spending reaches \$4,750. More than 30 million Medicare beneficiaries were enrolled in Part D plans in 2012—with about 63 percent (19.7 million) in stand-alone plans (PDPs) and the remaining 37 percent (11.7 million) in Medicare Advantage plans with prescription drug coverage (MA-PDs).<sup>9</sup> An additional 6.2 million were in employer or union-sponsored plans with equal or better benefits, and more than 8 million had prescription drug coverage from the Department of Veterans Affairs and other sources. In 2013, there are a total of 1,033

<sup>6</sup> Kaiser Family Foundation, *Seniors' Knowledge and Experience with Medicare's Open Enrollment Period and Choosing a Plan*, October 2012 Issue Brief. [www.kff.org](http://www.kff.org)

<sup>7</sup> F. Heiss et al., "Plan Selection in Medicare Part D: Evidence from Administrative Data," NBER Working Paper Series, June 2012.

<sup>8</sup> C. Zhou and Y. Zhang, "The Vast Majority Of Medicare Part D Beneficiaries Still Don't Choose The Cheapest Plans That Meet Their Medication Needs," *Health Affairs* Vol 31(1): 2259–2265.

<sup>9</sup> MedPAC, *Report to Congress: Medicare Payment Policy*, March 2013.

PDPs serving regional or national areas, as well as 1,627 MA-PDs. However, more than three-fourths of all Part D enrollees have historically gravitated to about a dozen national plans. That is, a few plans have a large majority of enrollees, with an average monthly premium (weighted for enrollment) of about \$40.

Medicare Part D's most generous coverage is reserved for the roughly one-third of enrollees with incomes below 150 percent of federal poverty level who qualify for the LIS benefit. Indeed, MedPAC found that in 2010, 56 percent of program costs were devoted to covering these enrollees, who are more likely to have multiple chronic conditions.<sup>10</sup> About 10 to 14 percent of non-low-income subsidy enrollees reached the Part D coverage gap ("doughnut hole") each year from 2006 to 2010, where they faced the full cost of their prescription drugs, and less than 2 percent of those beneficiaries reached the catastrophic coverage level.<sup>11</sup> We know beneficiaries who reach the coverage gap may forgo needed medications, possibly leading to preventable adverse health outcomes, and higher overall Medicare costs.

#### **Changes Made under the Affordable Care Act**

The 2010 Patient Protection and Affordable Care Act (ACA) takes several important steps to protect current and future enrollees who fall into the coverage gap. In 2010 a \$250 rebate was sent to all non-low-income subsidy (LIS) Part D enrollees who fell into the gap. Starting in 2011 the doughnut hole began to close through a combination of contributions from Part D enrollees, Medicare, and brand name drug manufacturers.

By 2020, non-LIS Part D enrollees will be responsible for 25 percent of their prescription drug costs throughout the time they meet their deductible to the time they enter catastrophic coverage, effectively eliminating the coverage gap. In addition, the growth rate for the Part D benefit's high catastrophic spending threshold, which is the amount a beneficiary must spend out-of-pocket before considerably lower coinsurance applies, will be slowed from 2014 through 2019. In 2020, the growth rate will again rise with enrollees' per capita drug spending.

The ACA also established a regulatory pathway that will allow the FDA to approve generic versions of biologic drugs, or biosimilars. Biologics, derived from living organisms, are in their early stages in the U.S., but are among the fastest growing and highest priced drugs. Such drugs, usually administered by injection, are increasingly used for chronic diseases that primarily affect older populations such as rheumatoid arthritis, multiple sclerosis, and certain cancers. These factors, combined with the current lack of generic alternatives, lead biologics to be among the most expensive prescription medicines on the market.

The ACA provides innovator biologic manufacturers with 12 years of market exclusivity before biosimilars can be approved. Presently, a very small but growing proportion of enrollees use these most expensive therapies, which are commonly assigned to a drug

<sup>10</sup> L. Summer, J. Hoadley, and E. Hargrave, *The Medicare Part D Low-Income Subsidy Program: Experience to Date and Policy Issues for Consideration*, Kaiser Family Foundation, September 2010. Also see, MedPAC Report, March 2013.

<sup>11</sup> C. M. Gbarayor, Ph.D., MPH, CMS Presentation, *Plan and Beneficiary Characteristics Associated with the Coverage Gap and Catastrophic Phase*, March 2012. <http://www.cmsdrugshealthplanevents.org/cms/index.php/events/cms-2012-medicare-prescription-drug-benefit-symposium/>

plan's "specialty" tier. Within Medicare Part D, users of biologics and other specialty drugs pay coinsurance that ranges from 25 percent to 40 percent. These drugs' full costs can range from \$1,500 per dose to tens of thousands of dollars, or more.

CMS has reported that while most enrollees who reach the coverage gap do so in mid-year, those using specialty drugs are likely to do so just a few months into the benefit year. Thus, they would quickly pass through to the catastrophic phase, where their drug costs are substantially covered by their plan and Medicare. While the trend nationally is for greater reliance on specialty drugs to treat chronic conditions, CMS last released a "top 10" list of such drugs for Part D enrollees based on the 2008 plan year. This prevents a timely analysis of current and projected cost trends in this area, at both the Medicare beneficiary and program level. One economic point is certain – specialty drugs' prices are rising at an annual rate of about 18 percent across all U.S. patients, a rate much faster than those of non-specialty drugs.<sup>12</sup>

#### **Assistance for Low-Income Beneficiaries**

Among the most important protections in Part D is the extra help provided by the low-income subsidy (LIS) to those least able to afford their drug costs. Around 11 million beneficiaries are currently receiving the LIS, but CMS has estimated that approximately 2 million other low-income beneficiaries are eligible but not receiving these subsidies. The LIS provides greatly reduced costs and no gap in coverage (no "doughnut hole") for beneficiaries with incomes below 150 percent of the federal poverty level (\$17,235 for individuals in 2013).

We are pleased the LIS benefit is providing essential help with premiums and copays to millions who otherwise might go without lifesaving medicines because of cost. We commend CMS for providing auto- and facilitated enrollment in LIS for people enrolled in Medicaid, a Medicare Savings Program (MSP), or receiving Supplemental Security Income and deemed eligible for LIS. We also applaud CMS for waiving the late enrollment penalty for anyone found eligible for LIS. We similarly appreciate steps SSA has taken to minimize the burden of annual LIS eligibility redeterminations.

However, LIS protection has still not reached too many low-income beneficiaries. More than 2 million beneficiaries are eligible for low-income subsidies but not receiving them, a finding that has been attributed to a variety of factors.<sup>13</sup> AARP is concerned by new research, published this month, that found more than 42 percent of persons eligible for the LIS were not enrolled in Part D. Those at older ages, with poorer cognitive skills, and poorer ability in math skills were least likely to enroll.<sup>14</sup> One particular source of concern is the asset test. To be eligible for the LIS in 2013, beneficiaries can have no more than \$13,300 in savings, or \$26,580 for a couple, no matter how low their income or how high their other living expenses. These amounts are hardly enough to get people through

<sup>12</sup> IMS Institute for Healthcare Informatics, *Declining Medicine Use and Costs: For Better or Worse? A Review of the Use of Medicines in the United States in 2012*, May 2013.

<sup>13</sup> L. Summer, J. Hoadley, and E. Hargrave, *The Medicare Part D Low-Income Subsidy Program: Experience to Date and Policy Issues for Consideration*, Kaiser Family Foundation, September 2010.

<sup>14</sup> I. Kuye, R. Frank, J. McWilliams, "Cognition and Take-Up of Subsidized Drug Benefits by Medicare Beneficiaries," *JAMA Internal Medicine*, (online) May 6, 2013. <http://www.jamainternalmed.com>

retirement, and anyone who saved even one dollar over these limits is not eligible for LIS. That is why AARP has consistently opposed the asset test.

Asset tests directly contradict efforts to encourage people to save by penalizing those who, despite very limited incomes, manage to put away a small nest egg for retirement. We should encourage people to save for retirement, not penalize those who do. According to the SSA, nearly 30 percent of LIS application denials in 2007 were due in part to excess assets.<sup>15</sup> Asset tests are also a serious barrier to enrollment, even for those who meet its limits, because it makes the application process daunting and invasive. Part D enrollees may not understand what information is required; they may have difficulty obtaining the information; and the need to verify the information can be time-consuming.<sup>16</sup>

#### **Medication Therapy Management**

Another important Part D feature that can help enrollees get the most value from, and avoid problems with, their medications is medication therapy management (MTM) programs. AARP supports the role of MTM programs in helping targeted Part D patients to avoid drug-related problems. Unfortunately, MTM programs under Part D have met with mixed success so far despite positive return-on-investment with MTM in some programs outside of Part D.<sup>17</sup>

One of the most important parts of any MTM program is the comprehensive medication review, where a pharmacist or other MTM provider reviews all of a patient's medications, documents recommended changes, and communicates them to prescribers. Such a review is mandatory for all MTM-eligible persons. Older adults may have many reasons for not adhering to their treatment plans, such as: forgetfulness, complicated regimens, fear of side effects, and cost.

However, CMS reported that in 2010, only 8 percent of those eligible accepted a plan's invitation to receive a comprehensive medication review. Why are so few patients accepting this free service? AARP realizes that patients may be more responsive to an invitation for MTM services if issued from a doctor or community pharmacist, with whom a patient may have a trusted relationship – rather than from the drug plan, as is current practice.<sup>18</sup> Better integrating MTM into the doctor-patient encounter, rather than as a freestanding service that may not be offered until long after a prescription is filled (or not filled, if adherence is a problem), could help promote MTM's value across Part D.

<sup>15</sup> GAO, *Medicare Part D Low-Income Subsidy: Assets and Income are Both Important in Subsidy Denials, and Access to State and Manufacturer Drug Programs is Uneven*, September 2008.

<sup>16</sup> L. Summer, J. Hoadley, and E. Hargrave, *The Medicare Part D Low-Income Subsidy Program: Experience to Date and Policy Issues for Consideration*, Kaiser Family Foundation, September 2010.

<sup>17</sup> A CMS pilot involving medication therapy management for Connecticut Medicaid patients found that almost a third of drug-related problems were due to inappropriate or unnecessary medications; and one-quarter were due to lack of adherence. Following several patient-pharmacist consultations to resolve many of these problems, the savings to CT Medicaid were found to be more than \$1,120 per patient on drug costs, and over \$470 per patient on medical, hospital, and emergency department expenses. M. Smith, "In Connecticut: Improving Patient Medication Management in Primary Care," *Health Affairs*, Vol. 30, No. 4 (April 2011), p. 646-654, <http://content.healthaffairs.org/content/30/4/646.abstract?sid=9f006ebf-1d13-4c27-bb60-ae88ad7e59f4>.

<sup>18</sup> N. Lee Rucker, *Medicare Part D's Medication Therapy Management: Shifting from Neutral to Drive*, AARP Public Policy Institute, June 2012. <http://www.aarp.org/health/medicare-insurance/info-06-2012/medicare-part-d-mtm-AARP-ppi-health.html>

Therefore, we are still learning a great deal about how Medicare Part D is affecting how people actually use medicines, and their effects on other costs of the Medicare program. For example, if drug-related problems cause a patient to land in the emergency room, or to undergo preventable procedures such as diabetic amputation, Medicare will likely incur those potentially larger downstream medical costs.<sup>19</sup>

### **Prescription Drug Safety**

CMS has stated that Part D “must balance the need to combat fraud, waste and abuse and at the same time ensure our beneficiaries have sufficient access to medically necessary prescription drugs.”<sup>20</sup> Examples of such possible fraud, waste and abuse were described in this month’s *Pro Publica* investigation, “Dangers Found in Lack of Safety Oversight for Medicare Drug Benefit.”<sup>21</sup> Better understanding and responding to such challenges are part of Part D’s evolution. For AARP members and Part D enrollees, these challenges may not be transparent – but that makes them no less important. Part D plans must currently report to CMS on their performance on eight patient safety measures.

To enable more consistent oversight by CMS and Part D plans, AARP believes we should consider requiring academic detailing on specific classes of medicines that are prone to misuse or inappropriate use in populations of Part D enrollees. The Agency for Healthcare Research and Quality (AHRQ) already supports a National Resource Center for Academic Detailing, which works with both public and private organizations to address their specific needs.<sup>22</sup> We should also expand the charge for the U.S. Pharmacopeial Convention (USP) “Model Guidelines” role – currently conducted under contract to CMS, as specified in the law enacting Part D<sup>23</sup> – to provide unbiased guidance to plans on specific drug safety issues. With input from diverse stakeholders, the USP is charged with identifying categories and classes of drugs that can be used by Part D plans in developing their formularies.<sup>24</sup>

### **Areas of Concern**

#### **Cost-Sharing**

Older Americans use prescription drugs more than any other segment of the U.S. population, and unfortunately many older Americans—particularly Medicare beneficiaries—continue to struggle to afford their prescription medications. In 2011, one-fifth of persons age 65 years and older asked their doctor for a lower-cost medication.

<sup>19</sup> Nationally, poor adherence has been estimated to cost up to \$290 billion/year, according to New England Healthcare Institute (NEHI).

<sup>20</sup> “Medicare Part D: Instances of Questionable Access to Prescription Drugs,” Government Accountability Office, Sept. 2011, GAO-11-699, <http://www.gao.gov/products/GAO-11-699>

<sup>21</sup> *The Washington Post*, May 12, 2013, [http://www.washingtonpost.com/national/health-science/dangers-found-in-lack-of-safety-oversight-for-medicare-drug-benefit/2013/05/11/067a10ae-b8ec-11e2-aa9e-a02b765ff0ea\\_story.html](http://www.washingtonpost.com/national/health-science/dangers-found-in-lack-of-safety-oversight-for-medicare-drug-benefit/2013/05/11/067a10ae-b8ec-11e2-aa9e-a02b765ff0ea_story.html)

<sup>22</sup> <http://www.narcad.org/about/>

<sup>23</sup> Medicare Modernization Act Section 1860D-4(b)(3)(C)(ii)

<sup>24</sup> <http://www.usp.org/usp-healthcare-professionals/medicare-model-guidelines>

That rate was even higher among near-poor older adults, with 24 percent requesting a lower cost alternative, according to the National Center for Health Statistics. Fortunately, Medicare Part D plans have helped to drive the overall generic prescribing rate from 61 percent in 2007 to 74 percent in 2010 (MedPAC, March 2013). However, the high cost of many brand name prescription drugs and associated cost-sharing can result in beneficiaries delaying or even failing to fill a prescription. According to a 2012 study by AARP's Public Policy Institute, the average annual increase in retail prices for 217 brand name prescription drugs widely used by Medicare beneficiaries was 8.3 percent in 2009. In contrast, the retail prices for 185 generic prescription drugs widely used by Medicare beneficiaries fell by an average of 7.8 percent.<sup>25</sup>

Making sure Part D beneficiaries can afford their prescriptions is essential as we continue to assess the program and how well it is working, and as we consider new policies to help further reduce costs. From the beneficiary perspective, Part D enrollees are now facing a more complex benefit structure than originally implemented. Nearly 70 percent of plans now have five or more different cost-sharing tiers. Where "preferred" and "non-preferred" designations previously were reserved for brand-name drugs, in some plans they are also applied to generics. In 2013, one-quarter of brand-name drugs require pre-approval (or "prior authorization") from the plan to use them, up from 20 percent in 2010.<sup>26</sup> Further, while recent years have featured some Part D plans offering deeply-reduced monthly premiums, per-prescription cost-sharing has increased. Since 2006, the median cost-sharing for a non-preferred brand-name drug has increased 67 percent, from \$55 to \$92 in 2012. Cost-sharing for "preferred" brand-name drugs increased 46 percent during the same period, from \$28 to \$41.<sup>27</sup>

#### ***Utilization Management***

Prescription drug plans have increasingly relied on a variety of utilization management tools to control costs such as quantity limits, prior authorization, and step therapy to manage enrollees' use of formulary prescription drugs.<sup>28</sup> While AARP appreciates these efforts are helping to promote safe and appropriate use, we should remain vigilant that utilization management is being used appropriately and not negatively impacting enrollee access to necessary prescription drugs.

#### ***The Low-Income Subsidy***

MedPAC recently reported that payments for the LIS population continued to be the largest component of Medicare Part D spending in 2011. In addition, a substantial share of other Part D spending categories also reflects benefits for LIS beneficiaries.<sup>29</sup> While AARP

<sup>25</sup> S. Schondelmeyer and L. Purvis, *Rx Price Watch Report, Trends in Retail Prices of Prescription Drugs Widely Used by Medicare Beneficiaries 2005 to 2009*, AARP Public Policy Institute, March 2012. [http://www.aarp.org/health/drugs-supplements/info-08-2010/rx\\_price\\_watch.html](http://www.aarp.org/health/drugs-supplements/info-08-2010/rx_price_watch.html)

<sup>26</sup> CMS presentation, "2013 Prescription Drug Plans," Dec. 2012.

<sup>27</sup> J. Hoadley, L. Summer et al., "Analysis of Medicare Prescription Drug Plans in 2012 and Key Trends since 2006," Kaiser Family Foundation, Sept. 2012. <http://kff.org/health-reform/report/medicare-rx-drug-plans-2012-and-key-trends/>

<sup>28</sup> L. Purvis and N. Lee Rucker, *Open Enrollment 2013: Medicare Part D Benefits Improve but Premiums and Cost-Sharing Rise in Many Popular Plans*, AARP Public Policy Institute Fact Sheet, November 2012. <http://www.aarp.org/health/medicare-insurance/info-11-2012/open-enrollment-2013-medicare-AARP-ppi-health.html>

<sup>29</sup> MedPAC, *Report to the Congress: Medicare Payment Policy*, March 2013.

appreciates that LIS-related Part D spending is a source of concern, we believe recent recommendations to modify prescription drug copayments for LIS beneficiaries may be premature. Instead, we recommend that research be undertaken to help gain a better understanding of what is driving LIS beneficiaries' utilization in order to ensure that any proposed changes to the LIS benefit will not negatively impact low-income beneficiaries' access unnecessarily.

#### ***Income Related Premiums***

The ACA added an income-related feature to the premiums for the Part D program, including a 10 year freeze on threshold levels, and further modifications to the current income-related premiums have been proposed as part of several deficit reduction plans. Under some proposals, the current freeze on income thresholds – starting at \$85,000 for an individual and \$170,000 for a couple – would be extended. If the income thresholds are frozen over a longer period of time, a growing share of elderly and disabled people who would not be considered high income by today's standards would face higher premiums.

AARP does not support making more Medicare Part D enrollees pay higher premiums based on their income. Seniors in Medicare have already paid into the system through payroll taxes—and those with higher incomes paid more into Medicare over their lifetimes. In many cases, seniors with higher incomes are still working and paying Medicare taxes—often because they do not have the savings they need to retire. Expecting them to pay more in premiums even as they continue to work and pay income and payroll taxes penalizes those who wish to work longer. AARP is also concerned that those with higher incomes may simply choose not to participate in the Medicare Part D program if asked to pay too much. This kind of risk selection could fundamentally change the nature and quality of the Medicare Part D program.

#### ***Appeals Process***

AARP appreciates the improvements that were made to the Medicare Part D exceptions and appeals process as part of the ACA, which requires plans to have a single, uniform process and to provide instant access to this process through a website and toll-free number. However, AARP believes that additional changes could further help reduce enrollees' confusion and expedite the exceptions and appeals process. For example, plans could be required to provide a personalized notice at the pharmacy counter that provides a clear explanation of why a prescription was refused.

#### ***Additional Steps Needed to Reduce Costs***

AARP has long-advocated for changes to the Medicare program that will help beneficiaries and improve the overall program. We urge Congress to enact legislation that will lower overall costs in the Part D program rather than adopt policies that reduce coverage or simply ask older Americans to pay more for their care.

#### ***Rebates***

AARP supports the Medicare Drug Savings Act requiring prescription drug manufacturers to provide rebates for drugs provided to Medicare Part D LIS beneficiaries who are dually eligible for Medicare and Medicaid. Prior to the enactment of the MMA, dual-eligibles received their prescription drugs through the Medicaid program, and thus, their drugs were subject to mandated manufacturer rebates. A recent comparison of 100 brand name drugs under Medicaid and Medicare Part D found that Medicaid rebates required by law reduced expenditures by 45 percent for the drugs under review. By comparison, Medicare Part D rebates secured by private drug plans reduced expenditures by only 19 percent.<sup>30</sup>

AARP is pleased to support this legislation, which focuses on constructively reducing costs, and has been estimated to save \$141 billion over the next ten years, without negatively impacting Medicare Part D benefits or shifting costs on to Medicare beneficiaries, half of whom live on annual incomes of \$22,500 or less. AARP looks forward to working with all Members of Congress to enact this sensible legislation to improve the fiscal stability of the Medicare program while protecting beneficiaries.

#### ***Secretarial Negotiation***

Currently, the Part D program relies upon negotiations conducted by individual prescription drug plan sponsors to obtain lower drug prices. AARP has consistently supported legislation that would enable the Secretary of Health and Human Services to use the bargaining power of Medicare's 49 million beneficiaries to further negotiate for lower prescription drug prices, which is especially important where there are no generic alternatives. More must be done to strengthen Medicare Part D plans' ability to secure lower prices for beneficiaries and the Medicare program.

#### ***Biologic Drugs***

AARP supports reducing the exclusivity period for biologic drugs. Biologic drugs hold the promise of treating some of the most serious diseases—such as multiple sclerosis, rheumatoid arthritis, cancer and others—that often affect older populations. The daily costs associated with biologics are approximately 22 times higher than the daily costs associated with small molecule drugs<sup>31</sup>; annual costs for biologic drugs can reach as high as \$400,000.<sup>32</sup> Persons who are prescribed biologic drugs—particularly those with chronic conditions who require such treatment indefinitely—may find the drugs unaffordable and decide to forgo them completely. The costs associated with biologic drugs are also a large and growing burden for federal programs like Medicare.

Specialty drugs, many of which are biologics, accounted for 10 percent, or \$5.6 billion, of the \$54.4 billion in total prescription drug spending under Medicare Part D plans in 2007. Among all Part D enrollees who used at least one specialty drug in 2007, 55 percent

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<sup>30</sup> Department of Health and Human Services, Office of the Inspector General, *Higher Rebates for Brand-Name Drugs Result in Low Costs for Medicaid Compared to Medicare Part D*, August 2011.

<sup>31</sup> A.D. So and S.L. Katz, "Biologics Boondoggle." *New York Times*, March 7, 2010.

<sup>32</sup> M. Herper, "The World's Most Expensive Drugs," *Forbes*, February 22, 2010.

reached the catastrophic coverage threshold, after which Medicare pays at least 80 percent of all drug costs.<sup>33</sup>

The period of market exclusivity granted to brand name biologic manufacturers by the ACA is twelve years. AARP and many others, including the Federal Trade Commission, have long stated this period of exclusivity is excessive and serves to over-compensate brand-name biologic companies while keeping much-needed biosimilar drugs from coming to market. Were the exclusivity period reduced from twelve years to seven years, it could result in billions of dollars in savings not only for beneficiaries and the Medicare program, but for employers and other health care payers.

#### **Conclusion**

The Medicare prescription drug benefit – including the closure of the Part D coverage gap – represents the most significant change to Medicare since the program began in 1965. The extra financial help provided to people who most need it through the LIS is a key component, but it is critical we eliminate the asset test that is penalizing people who save for retirement and imposing a barrier to enrollment in the LIS. In addition, reestablishing drug rebates like those obtained by Medicaid under the program and granting secretarial negotiating authority is needed to help keep the benefit more affordable as we move forward.

AARP stands ready to work with Congress to find ways to keep drug coverage affordable Medicare beneficiaries. However, we should focus on efforts to hold down costs and not efforts that simply shift costs in the form of higher premiums to certain beneficiaries. In addition, AARP opposes further income relating premiums or copayments that penalize saving and could begin to erode public support for this important program. Medicare's success has been largely attributed to its widespread acceptance by all providers and Americans across the income spectrum.

AARP is committed to strengthening the Part D drug benefit and working towards the enactment of responsible changes to improve access and reduce costs. We look forward to working with members of Congress from both sides of the aisle to improve the Medicare Part D prescription drug benefit and to ensure that all older Americans have access to affordable prescription drugs.

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<sup>33</sup> GAO, *Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier*, January 2010.

The CHAIRMAN. Thank you to all of you.

We are going to get into questions, and it will help flesh out, since Senator Collins and I did not make an opening statement, setting the table for the discussion today. And I am going to defer my questions until our colleagues have asked theirs.

Senator Collins.

Senator COLLINS. Thank you very much, Mr. Chairman. Let me begin by commending you for holding this series of hearings as we approach the 10th anniversary of the Medicare Modernization Act of 2003.

I was proud to vote for that legislation, and I think that it is possibly—no, I am going to go out on a limb here and say it is the only entitlement program in history where the actual experience has produced much lower costs both for the government and for beneficiaries than was initially estimated. Usually, it goes the other way when we create a new benefit. So that is good news indeed as is the high satisfaction rate.

Nevertheless, there are some very important issues that we need to explore as we approach the tenth year of this program.

Dr. Woerner, I was very interested in hearing your experience in counseling beneficiaries. Many Part D plans now use medication utilization management tools such as prior authorization, medication substitution or quantity limits that restrict a beneficiary's access to prescription drugs.

I have heard concerns from my constituents that some drug plans have what I refer to as a Fail First Policy in which a beneficiary may be prescribed a more expensive medication but first has to use a lower cost drug or a plan-preferred medication and actually experience the failure of that medication before they are allowed to use the medication that their doctor wanted to prescribe in the first place.

I know of an elderly woman in Maine who had the experience of having side effects from a drug that was the lower cost drug and had a terrible cough for a month from it. When she was able to switch to the drug that her doctor originally prescribed, she was fine.

Is this common in your experience?

And do you have any suggestions—and I am going to ask all of you this question. Do you have any suggestions for how we can strike the right balance between making sure that plans do have the ability to legitimately control costs and yet not put our seniors through a situation where they are going to have to experience the failure of a drug before they can get the drug their doctor knew was the preferred medication in the first place?

Ms. WOERNER. You have it exactly right, Mrs. Collins. We get many, many calls from people who have gone through that process. Their doctor has prescribed a drug, and the plan says before we will cover that drug you must try sometimes two or three other drugs.

Now very often the caller will tell me, I have tried those drugs, and I had a terrible rash when I got that, or I had a terrible intestinal problem.

They have already been through those, but in order to convince the plan they need to get documentation from the doctors who pre-

scribed those earlier medications. That is not always possible or certainly not always easy to do.

So I would say that is a very common problem among the callers that we get.

Senator COLLINS. Thank you.

Ms. WOERNER. I am not sure I have the ability to answer the question of how to improve the lot of these people who really need the drug that the doctor has prescribed and still have some cost containment issues.

Senator COLLINS. Let me ask the rest of your panelists.

It is very good to have you verify that you get those kinds of calls that my office does too, and we have gotten them even when the physician has written the letter saying the person needs this particular drug.

Why don't I just quickly go down the panel?

Dr. Hoadley.

Mr. HOADLEY. Yes, I think that there are some potential things you can do, and one of the things is just to understand how often this happens. We know; we have good data on how many drugs these limits apply to. What we do not know is how many people run into these issues in a simple way and how many run into them in a way that is more complicated and takes more steps to resolve. So just more information would be better.

I think plans could be forced to target these measures better. There are some cases where there probably are appropriate measures. There are safety issues in some cases, and in those situations, certainly, there should be—these measures are appropriate. But if plans targeted them to a smaller, more select set of drugs, that would probably help.

We also need clearer and simpler processes, both to go through this and to appeal it. But you hear the same thing from doctors; you know, the paperwork involved to request one of the exceptions or an authorization or to document that fail first or step therapy kind of situation is a real burden on doctors.

And my last comment, I guess, goes exactly to this point that you were talking about a moment ago, which is you have already tried that drug before. And a better method to track this, certainly in one specific area, is if a person moves from Plan A to Plan B, that information that they tried and proved that information to Plan A should be carried along to Plan B. Obviously, if somebody is new to the program, then you are going to have to involve the doctor in some way. But a better way to carry the history forward—and maybe with some of the electronic tools we have got more ability to do that than we did in the past.

But I think there are things that are not easy, simple solutions, however.

Senator COLLINS. Thank you.

Mr. SMITH. Thank you, Senator.

I will start exactly where Dr. Hoadley left off.

I think that there is a real opportunity to improve the situation by bringing along information as individuals transfer among plans, and that is something that we have supported. And that also gives plans—the new plan—an opportunity to look at the full range of utilization and see if there are other issues that need to be worked

out. So I think that would be a step forward for the program and for beneficiaries.

I will also note that CMS has looked at some plan practices, and its call letter this year indicated that, you know, there are some instances in which we think you are overdoing it and we really do not want to see that. I think it leaves plenty of leeway for the plans without overdoing it.

And it may be that we should be looking more to identify are there plans that are outliers; are there plans where we are seeing a particular pattern of problems, and then really looking intensively.

And then, finally, I would say that it may be—and here, I am quite honestly thinking out loud. It may be that we should think that in some instances maybe the presumption should be in favor of the beneficiary so they do not have to fail first, and then you can unwind the issue later on.

Senator COLLINS. Thank you.

I know my time has expired, but I am going to ask for the record if you would provide me with AARP's—

The CHAIRMAN. No, go ahead.

Senator COLLINS. Thank you.

Mr. Romasco.

Mr. ROMASCO. Thank you, Senator.

I think a lot of the things we are hearing here are transparency, information, portability.

And one thing AARP has always supported is the primacy of the relationship between the doctor and the patient. My personal experience is the doctor understands what I need and what I have done before. And the only thing I would add is they make good judgments based on the total cost and impact.

Studies at Johns Hopkins have shown when physicians see the total cost impact they make a good judgment—what is best for you medically combined with what the cost is.

So I think those things, in combination with what my fellow panelists would do, would improve the situation.

Senator COLLINS. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Warren.

Senator WARREN. Thank you, Mr. Chairman. Thank you, Ranking Member Collins. I really appreciate your having this hearing.

And thanks to all of you for being here.

Now I want to look at another part of this. According to CMS, 93 percent of traditional Medicare spending goes toward the care of beneficiaries with multiple chronic conditions, and prescription drugs are clearly a vital part of their care. They allow us to manage successfully many chronic diseases, thanks in part to up-front investments and innovation in the pharmaceutical and biotechnology industries.

But, unfortunately, just because a drug is prescribed does not mean a drug is actually taken according to the terms of that prescription, and this matters when we are trying to get better outcomes at lower costs across our health care system.

I understand—and I think you alluded to this study; it may have been you, Mr. Smith—a study by Rand researchers found that pa-

tients at high risk for cardiovascular disease who reliably took their cholesterol-lowering drugs had about 35 percent fewer hospitalizations compared with those who did not. That is a really remarkable difference just brought on by taking your drugs.

And I understand the new CBO study shows that increased prescription drug use actually reduces the cost of other health care services.

So one important way to improve effective drug use is through the medication therapy management programs that you spoke about. Medicare Part D plans, as I understand it, require these programs for seniors and those with multiple chronic conditions to help with their medication regimens, hopefully, increasing adherence and assuring that the drugs that are prescribed are taken effectively for each individual.

But what I want to know is, how can we improve on the medication therapy management programs and if there are other evidence-based strategies that we might employ to get more people taking their prescription medication successfully?

Mr. Smith, could I start with you on that?

Mr. SMITH. Certainly, Senator. Thank you very much for the question.

This is an area that I think has tremendous potential, and it is one of those areas in health care where you can say, you know, we can actually get the cost savings we all want with better outcomes for the beneficiary. And you really cannot argue with that.

So, in terms of medication therapy management programs, we are very encouraged to see CMS publish the first study this year about the experience with medication therapy management programs in Part D, and it found that for COPD and congestive heart failure the medication therapy management programs were, in fact, helping lower hospitals costs. So that is really good news—better quality care, lower costs overall, better results for the beneficiary.

Senator WARREN. And, Mr. Smith, let me just interrupt just for one second just because I want to make sure I understand.

Mr. SMITH. Yes.

Senator WARREN. It is lower cost on those two diseases—

Mr. SMITH. Yes.

Senator WARREN [continuing]. Because those were the two studied—

Mr. SMITH. Yes.

Senator WARREN [continuing]. Not because they found that there were not lower cost in other areas.

Mr. SMITH. Yes, I believe that is right.

So I think a couple of points, and I will leave lots of time for my colleagues.

A couple of points that I would suggest are I think we actually need a lot more research. We need to know more about what is going on with the medication therapy management programs, which strategies seem to work well, under what circumstances, so that there can be broader learning and we can take advantage of this opportunity.

You asked about other strategies. One that might be related to taking advantage of medication therapy management that has attracted a good amount of interest lately is called synchronization.

So you may have a senior who is taking five different medicines. They have to go to the pharmacy five different times during the course of a month.

If you put it all together—and there is now software that will do it—you get a couple of benefits. The senior only has to go once, and you see all of those prescriptions together. So, if there are any issues in the contraindications among the medicines and so forth, you have an opportunity to take care of them.

So I think looking at strategies like that—learning more about how MTMP is working and how its successes can be extended—is important.

And we also need to learn why CMS reported that a fair number of seniors who were contacted for medication therapy management were not taking advantage of the opportunity offered. We need to learn about that so that we can work through it.

Senator WARREN. Good, very helpful.

Mr. Romasco, would you like to add?

Mr. ROMASCO. Just a couple of thoughts—one is I think everything Mr. Smith said is worthy of that, but the first barrier to compliance is making sure you can afford the drug in the first place, which is why a lot of the suggestions that we make here focus on keeping the costs down and potentially lowering the cost—because that is the first barrier, because the number of stories of people actually noncomplying on a conscious level, to basically spread their Lipitors over 60 days versus 30 days, is unfortunately all too common.

The second thing is compliance is habit-forming. Basically, if you are taking medication when you are 60 under a health care company plan, you will probably be more likely to keep doing it when you retire and are under Medicare. So we need to look at the entire compliance issue and learn from how the private plans are actually encouraging compliance as they have employers sponsor things.

So I think those two issues—making sure the cost is low enough to make sure that you can afford the drug in the first place, and some of the suggestions that Mr. Smith made I think are worthy—understanding why people skip it even when they know it is good for them.

Senator WARREN. Would it be, Dr. Hoadley, if you could very quickly add anything more? We have got good ideas here.

Mr. HOADLEY. Yes, I would easily second the comments I have heard on affordability matters a lot.

And we need to know a lot more about what the plans are doing in their MTM programs, and CMS is starting to put that record together.

CMS also includes, or has proposed to include, more information in their Star Rating System, and this could be eventually a tool by which plans could compete over their ability to do this well. And so a consumer could say, ah, this plan has a better track record at helping to improve adherence.

And I think there are some solutions where technology could play a role—the synchronization that Mr. Smith talked about.

But even other things about taking the medications—if you are a person with those multiple chronic conditions and you have got four, five, six, eight, ten different drugs to take and each one says

with food, on an empty stomach, this and that, helping that patient—maybe this is a role that pharmacists could play, or nurses, as part of a medical team. Help the person figure out what is the right way to array their medications across the day. Make it very easy to do that.

People who are running into more disability problems, it is intimidating to look at that array of drugs. And, did I already take that one?

And how can we provide more aids and tools to help people take them together. Get them lined up. Maybe figure out some of them are not needed. Get the important drugs and really build some assistance to the patient in trying to use their drugs well.

Senator WARREN. Very thoughtful.

And I am out of time here. Dr. Woerner, did you just have a brief remark you would like to add?

Ms. WOERNER. Well, just that our callers do not talk about being in such programs, and I am not sure what that means.

Senator WARREN. Good. That is a very helpful point about going back and understanding this.

I just want to thank you all. I think we have got some great ideas for how, if we make the right investments, we can get better outcomes at lower costs. And that has got to be where we are aiming.

Thank you, Mr. Chairman.

The CHAIRMAN. And I want to underscore what Mr. Romasco has said, that cost is still a major barrier. It is not unusual in Florida that a senior—fortunately, it does not happen very often, but a senior is making a choice between their medicine and food. And that should not be in America in the year 2013.

Senator Ayotte.

Senator AYOTTE. I want to thank the Chairman and Ranking Member for having this hearing and the witnesses for being here today.

I wanted to ask—I guess I would start first with Mr. Smith and anyone on the panel who has a comment on it.

The Affordable Care Act created what is called the Independent Payment Advisory Board, and this board was—it is unique. I do not know if it is unique in its structure, but in order to overturn decisions of the board you actually need a three-fifths vote of Congress. So it would not be simply how we would normally pass legislation—an up or down vote—if we disagreed with the recommendations of the board.

But also it contains a provision that a majority of the people making the decisions that would impact payments to Medicare providers—and, therefore, I think could also impact what recipients would receive, depending on what was covered. Those individuals, a majority, cannot be involved in treating patients or providing health care services to Medicare beneficiaries. So, obviously, they can serve on it but cannot be a majority who are making these decisions on what will be covered.

I raise the issue because I have heard from many physicians in New Hampshire, and provider groups, that they are concerned about IPAB and how it would impact seniors' care.

And just this past month 500 organizations, including several from New Hampshire—they really represent a diverse sector of the health care industry, small and large—wrote to Congress, urging us to eliminate IPAB.

As I understand it, PhRMA has previously expressed opposition to IPAB. I wanted to ask you why that is, also what impact you think that IPAB could have potentially on Medicare Part D.

And then certainly I would open it up to other panelists that have an opinion on this and would like to comment on it.

So thank you.

Mr. SMITH. Thank you for the question, Senator.

I think I would start at you are absolutely correct. We have expressed serious concerns about IPAB and opposition to IPAB, along with many, many others across the health care system and many other communities. And I think I would say that that starts with the fact that IPAB can make major changes to laws that Congress has passed without the usual checks and balances from Congress or the courts, and I think that that raises a lot of reasons for concern.

I would note that its advocates argue that IPAB will focus on savings through quality improvement, through the sorts of things that we were just talking about and that I think are an intelligent way to go.

But I think that is almost certainly wrong, and it is not because IPAB will be made up of short-sighted people. But the reality is it has to meet spending targets in one-year time frames, and quality improvements typically take longer to yield these kinds of savings.

And CBO itself has pointed out that it expects IPAB to focus on payment cuts, and I think within that it will focus very much on Part B and Part D because those are called out in the statute to be targeted. And I think that manipulating payment amounts in this fashion can, of course, have very significant effects on beneficiaries' access to care.

Today, because we have the market-based system we do in Part D—Mr. Romasco mentioned affordability around access—84 percent of all prescriptions in Part D last year were dispensed with a co-pay of \$10 dollars or less. And we have that market-based system that has driven these kinds of results.

But I do not think you are going to get that kind of result from this sort of board that has been created. I think it is going the traditional ways that really can significantly restrict access.

Senator AYOTTE. Thank you.

Do others have opinions or thoughts on IPAB?

Mr. HOADLEY. I would just observe that for the moment at least the low spending growth trend we have seen in the last couple of years has made the triggers that are built into that—even if the IPAB had been staffed and existed, it would make those kinds of deliberations unnecessary.

So maybe the observation to make here is that if we continue to maintain a track record like this particular program has maintained and do the kinds of things we have been talking about to keep it working well, then that will help make those deliberations unnecessary.

Senator AYOTTE. So we will not IPAB.

Mr. HOADLEY. We would not need IPAB.

Senator AYOTTE. But if we ever do, I, obviously, want to make sure that it does not create—

Mr. HOADLEY. Understand.

Senator AYOTTE [continuing]. A situation where people are not—you know, it creates—one of the concerns is, obviously, just the super majority that is required.

Dr. Woerner, I do not know if you have a thought on IPAB.

Ms. WOERNER. I do not think I have anything to contribute on that topic.

Senator AYOTTE. Thank you.

Mr. Romasco.

Mr. ROMASCO. I think the legislation clearly calls for it as a failsafe because the real issue here is health care costs overall. If we cannot get them to grow at the economic rate or lower, that is where our problem is. So that is sort of a failsafe mechanism.

And I think Dr. Hoadley's idea that it is there in case as opposed to mandatory is worthy of consideration. We need a mechanism that continues to focus on the \$2.7 trillion we are spending and whether or not that is growing too fast and effective.

Senator AYOTTE. Now I appreciate that, but if the failsafe is there and you all are concerned—obviously, rightly so, as all of us are—in terms of what is the care that people receive, I want to make sure that that failsafe has accountability here. So, if decisions that are made are not correct, you know, this Congress can correct them in the normal course.

And I am a supporter of actually ending it.

But I do appreciate all of you coming here today and thank you for the work that you are doing on Medicare Part D. Thank you.

The CHAIRMAN. Senator Wyden.

Senator WYDEN. Thank you, Mr. Chairman. And, Mr. Chairman, thank you for very timely leadership. I think this is a particular important time for us to look back.

And, Dr. Woerner, it is so great to have the Medicare Rights Center. I can remember days when all of us had Diane Archer on speed dial for the wonderful work that she had been doing for the rights of seniors.

And, welcome to all of you.

Recalling just for a minute the ferocious debate that took place when this legislation was first considered, I think you have to start with the proposition that at that time the level of desperation among seniors for some measure of assistance with their medicine was just extraordinary, and at that time it really felt like this debate had gone on for eons.

I mean, I can remember this back in the days when we were just getting the Gray Panthers off the ground in Oregon. We were talking about this very issue.

And I came to the conclusion at the time that we were really at a fork in the road and that if we did not take the opportunity to at least get started it would probably be eons more before we ever got this effort underway.

I told Senator Warren, I remember talking with Senator Kennedy, who of course worked for this for years.

So I voted for the legislation. The welts on my back for doing so took a couple of years to heal. But the reality is at least we have gotten started and we have been able to help a lot of people.

And, Dr. Woerner, your points with respect to the future are really spot-on.

I just want to ask a couple of questions here by way of what is ahead.

Now one of the major concerns today is how seniors are going to afford these specialty drugs—what are called, in effect—I guess the technical name is the specialty tier drugs. These were drugs that largely were not even on the boards back when this program got started—cancer drugs, arthritis drugs, MS drugs.

I have been very concerned, for example, about Xeljanz. This is a drug where the government played a very large role in its development. Pfizer, now the company with the drug, looking like \$25,000. That is a big lift for the seniors that Senator Nelson does such a good job advocating for.

What would be your counsel with respect to how to deal with these specialty drugs that are so expensive?

And I think, increasingly, they are going to be injectables and they are going to play a bigger and bigger role in the health care landscape.

So, your thoughts on holding down the costs of these specialty drugs for seniors would be how I would start.

Ms. WOERNER. Well, there is a particular problem with specialty drugs for people who are really in lower incomes. What happens is for other medications, if the doctor prescribes a particular medication that is in a high tier, not a specialty tier, the client can appeal to lower the tier, lower the price, if there is not another drug that that person can use instead.

Specialty drugs do not have that. One cannot appeal for a lower price for a specialty drug.

And we have had many callers who have needed one of the specialty drugs for conditions like multiple sclerosis, for example, who cannot appeal to the company because they are low-income.

One woman I recall was living on about \$1,700 Social Security income. She was above the level for the extra help—low-income subsidy, and that is not a lot of income. So she really had to choose between her multiple sclerosis drug at a very high cost and food or other everyday living expenses.

So I think the first thing would be to allow a process of the same kind of appeal that you have for tier appeals, lowering tier costs, apply to the specialty drugs.

Senator WYDEN. That sounds too logical for Washington.

[Laughter.]

Let us work with all of you. I want to see if I can get one other response.

And then I thought Senator Warren asked a very good question about chronic disease and medicine, and I would like to get that in if I can.

So why don't we have one more response?

Mr. SMITH. Sure. On the chronic disease issue and ways to move forward, Senator?

Senator WYDEN. Yes.

Mr. SMITH. Yes. So perhaps picking up where I left off, one of the issues with medication therapy management today, as it is set up in Part D, is who is targeted for medication therapy management. Right now, you have to have high drug expenditures, and in practice, you have to be taking a lot of different medicines.

So part of the issue there is that we may be missing people who are not adherent because they are not taking their medicines and they do not have the level of drug expenditure that triggers MTMP.

Maybe we ought to be looking at what is their total expenditure and what kind of conditions do they have and can MTMP be helping rather than just zeroing in the way we did. I think we have a lot of opportunity to make progress on cost and on quality by going these routes.

Senator WYDEN. My time is expired.

I hope that all of you as companies and advocates will also start to factor in that these drugs affect people differently. For years and years, medicine has always been based on the proposition that this drug will affect Harry and George in the same way, and Sally and Betty in the same way.

And I think this is particularly important in the area of chronic disease, where Senator Warren has made the important point that we ought to be focused more on patient management and relate to individuals. And to do that right, we are going to need to know more about the differential treatment of medicines for different people—what is really sort of the gun at least with personalized medicine, but where there is going to have to be a lot more work.

Senator Nelson, again, a big thanks to you for all the leadership.

The CHAIRMAN. Well, thank you, Senator Wyden, and thank you for bringing up the appeals process and for Dr. Woerner's excellent response.

I will give you an example. A lady in Florida, Ms. Beagles, when her drug for a brain tumor went into the specialty category and she had no appeal process, it went from \$30 a month to \$650 a month. And, obviously, there is a need now.

Any of the remaining three of you want to comment about the appeals process?

Mr. SMITH. Senator, I fully agree with Dr. Woerner's point. PhRMA has long been on record in support of treating the specialty tier in the same way as the other tiers are treated for this purpose.

The CHAIRMAN. Okay, let's move on to another subject.

Mr. Smith, you heard Mr. Romasco say that the very same drugs that Medicare used to pay for—

Mr. SMITH. Yes.

The CHAIRMAN [continuing]. When the prescription drug legislation was passed in 2003—

Mr. SMITH. Yes.

The CHAIRMAN [continuing]. Because those people that had been receiving their drugs under Medicare now are over age 65—

Mr. SMITH. Yes.

The CHAIRMAN [continuing]. They get their drugs in Medicare.

And now the price that the U.S. Government is paying is not the same. It is not the same to the degree of the statement by Mr. Romasco that it costs the U.S. taxpayer over 10 years an additional \$147 billion.

Now how can we justify that for these dual eligibles?

Mr. SMITH. So, Senator, thank you very much for the question, and I suspected I might get it. So I appreciate your putting it out there and the opportunity to respond.

Let me begin by noting that Medicaid has never been viewed as the benchmark for Medicare for any service. It has not been viewed as the benchmark for physician payment. It has not been viewed as the benchmark for hospital payment.

And I will also note that organizations such as Mr. Romasco's advocated aggressively for moving the dual eligibles out of Medicaid and into Medicare because of the restrictiveness and the uncertainty and the skimpiness that often accompanies Medicaid benefits.

I think that we also have something of an apples to oranges comparison in that there have been major policy changes that are not taken into account when these calculations are done.

So, for instance, since 2003, or since 2006 if you will, there are coverage gap discounts that the CMS actuary recently, or last year, estimated that just over 6 years, not the usual 10 that we are all used to, comes at a cost to the industry of about \$30 billion.

So, spun out over 10 years, that is going to be \$50 billion or \$60 billion. There is \$30 billion going into the Medicare Trust Fund that is paid by the industry.

So I think that taking Medicaid over here and only taking part of Medicare over here and not looking at the totality of Medicare does create a little bit of an apples and oranges—or a lot of an apples and oranges—effect.

Finally, I will add that we have strong, powerful purchasers with lots of tools out there to drive savings. They do drive savings. Part D costs today, for 2012, are 54 percent lower than was projected in 2004 after the program passed while Medicare as a whole has increased.

So Medicare deserves fair prices, good prices, savings. It is getting them. That is why CBO has knocked \$100 billion a year off the cost of the program in each of the last 3 years.

And these powerful, sophisticated purchasers are buying them in a market. We think that is the right way to do it because government price controls layered on top of the market, I believe, will significantly undermine the program's effectiveness, its competitive forces, that lead to good results for beneficiaries and will significantly undermine the U.S. industry's innovative capacity.

The CHAIRMAN. I want you to tell your employers that I give you an A for your response. If I were in your shoes, I would have liked to have been as articulate to respond as you do, but it does not cut it.

And it does not cut it when the U.S. Government is, in fact, a big purchaser that you talked about—

Mr. SMITH. Yes.

The CHAIRMAN [continuing]. In a competitive marketplace.

The United States Government gets that discount with Medicaid, which is almost as big a program eventually as Medicare drugs will be.

And the U.S. Government also gets that discount in the Veterans Administration, which is another multiple of tens of millions of veterans, each requiring drugs.

And, the U.S. Government also gets that discount through the Department of Defense.

So, when we talk about the competitive marketplace, clearly, since some of are invested with the idea that we are trying to get the biggest bang for the taxpayer's buck, and you have someone who is eligible here up until they get 64 years of age and 364 days, but on the 365th day they suddenly are eligible for those same drugs here, provided by the government.

And remember, the way that we are phasing in under the health care bill—the way that they are phasing in Medicare Part D for seniors—is that the Federal Government will continue to pick up more and more of the cost as the donut hole is shrunk, and as a result, what there ought to be is balance in the system.

Now I started my comments early on by complimenting you.

Mr. SMITH. Understood.

The CHAIRMAN. Complimenting you on what your industry is doing is absolutely fantastic because of the miracles that you are creating before our eyes in what you are researching and developing, and in no way do we want to lessen that R&D. However, we have come down to a basic question of dollars and cents for the taxpayer, and this is one that we are going to have to look at.

Now I, of course, took this on when we passed the health care bill, and I got beat in the Senate Finance Committee, but this issue is not going to go away. And so you should face that.

And that is especially so over the course of the next 7 years as the U.S. Government is picking up more and more and more so that, by 2020, 100 percent of the cost of the drugs in Medicare Part D on that donut hole are going to be absorbed for the senior.

Mr. Romasco, you look like you are ready to say something, and then I am going to turn to my colleagues here.

Mr. ROMASCO. I could not support the concept more fully. The U.S. Government is a huge purchaser, much bigger than any of the individual insurance companies. It continues to baffle me that it is like telling Wal-Mart they cannot negotiate with Procter and Gamble over the price of Tide. It just does not make sense.

I think the other example—and I think Mr. Smith alluded to it, and it is a very important issue about research and development—is there was a similar argument in the early eighties about the Hatch-Waxman Act which paved the way for generic drugs. Often-times, the industry made the argument that this would stifle R&D, and yet, through their ingenious market forces, we now have generic drugs, everybody is prosperous, the industry has grown, and they continue to be successful and profitable.

So I think that the concept of secretarial negotiating authority is a critical idea. I think shortening the generic biologic horizon from 12 to 7 years is another possibility. And the discount in the Act that your legislation supports is another way of keeping our eye on the ball as the affordability of the drugs, not only in Medicare but across the entire health system, is at stake.

The CHAIRMAN. Before I turn to Senator Collins, let me just make note; I wish Senator Wyden were here because going back on

the history of all of this, it is true that the prescription drug benefit was first authorized and set up in 2003 in the prescription drug bill, but there was another thing that was set up at that time, and it became very costly to the government.

And it was setting up a new delivery of Medicare through an insurance company called Medicare Advantage, delivered through an HMO, which is an insurance company.

And what happened in that 2003 legislation was insurance companies were given a 14 percent bump per senior citizen beneficiary of Medicare. That became so expensive that when the health care reform bill came along we had to save Medicare because it was going bankrupt, and one of the major reasons was that the Federal Government was paying out too much to the insurance companies, over and above Medicare Fee-For-Service. And that was leaned out over time through that health care bill.

So, in the history of this whole continuum here, we have one overstepping and that now being corrected, and that is why I bring up this prescription drug benefit where there is such a significant increase to the taxpayer on the bill, on the drugs delivered through Part D.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

I am going to follow up on the Chairman's very interesting questions in this regard because this is an issue where I can see both sides of it, frankly.

On the one hand, you look at the VA system, where government has used its purchasing power for years to negotiate prices. We do it in the Medicaid program. It was not just President Obama who has included this in his budget, but the Bowles-Simpson Commission also had the recommendation, which gives it some credibility in my eyes.

On the other hand, you can certainly look at the marketplace and say that we have 1,000 plans, there is lots of competition, and we have sophisticated insurers who are doing that kind of negotiation with very good results for the consumer since the prices are so much less for premiums than had been projected in the costs for government.

So I am truly of two minds about this and about which way is the better way to go.

So, Mr. Smith, from your perspective, since you can legitimately point to a successful program that has driven down prices with successful, sophisticated negotiators in these plans, but if it should not be extended, why do we have it in Medicaid and in the VA program?

Mr. SMITH. Okay. Thank you for that question, Senator.

So the first point I would make is that I think it is always possible to look somewhere else and find a different price point and say, why doesn't a different program get that price point?

Medicare is, in fact, just central to the U.S. marketplace. It is a much more significant program than both Medicaid and VA. And I think because we have statutory provisions that have set prices in those programs over the year because there are exceptional reasons for those programs does not mean that we can expect that we would have the same effect if we extended that to Medicare.

I think extending these rules for smaller programs that have exceptional circumstances—veterans and so forth—to Medicare would send very negative signals both into the Part D program and into the market as a whole.

I know that there is a view that it is really just easily affordable.

And I think that when I look at what McKinsey says, for instance, about pharmaceutical R&D, it says over the last—you know, in recent years, pharmaceutical R&D has not been earning a return on investment.

When I see what a slew of analysts say about pharmaceutical R&D that echoes what McKinsey has to say, I think that it is clear that we are at a point where this kind of policy would force choices. And it is going to force choices about R&D. It is going to change the fundamental nature of Part D with the potential to increase premiums, have more restrictive formularies and so forth. And it is going to change the nature of the industry as an economic driver.

Final point I will make is that those programs that we are often compared to—VA, Medicaid. Again, as I mentioned, there was a broad-based by the advocacy community to move prescription drug coverage out of Medicaid, into Medicare, specifically because of the shortcomings of the Medicaid program.

And I think we have heard today that while there are issues to be addressed, there is a broad endorsement of how well the program today is working for seniors.

And, second, I would note that many of those programs are very restrictive around access, far more so than Part D. Part D plans offer a far broader range of medicines than does VA. And, in fact, many veterans who have VA coverage are also enrolled in Part D, and they are using Part D because they are getting access to medicines that they are not getting in VA.

So I think we have a range of issues, but the most direct point I can make is that I think what is being proposed is, in some sense, a race to the bottom because there is an example over here of a program with a specific set of prices; it should be transported over here.

That has not been discussed around hospitals; it has not been discussed around doctors, where there are also dual eligibles. It has only been discussed around medicines.

And for the reasons I have stated, I think it does force real choices instead of being something that will be without consequence.

Senator COLLINS. With respect to the vital research and development on new drugs that the pharmaceutical industry does, isn't the American consumer really subsidizing that for the rest of the world?

I mean, most countries do have controls on the cost of medications. I am very attuned to that issue, living in a border state with Canada.

Mr. SMITH. Absolutely.

Senator COLLINS. And, in a way, it is the American consumer that is paying for that cost, are we not?

Mr. SMITH. Sure. Well, I think that American consumers pay for the cost, and I actually think consumers in foreign countries end up paying for the cost.

Senator COLLINS. How?

Mr. SMITH. With significant restrictions on access to medicines. We also have a situation in which the global center of the bio-pharmaceutical research sector through the 1980s and so forth was in Europe. Today, the U.S. greatly outweighs Europe. And I think the fact that we have market-based pricing rather than government price controls is a significant part of the reason that that is the case.

I will also note, finally, that our market-based system creates and drives incentives to use dollars where they are valuable.

So, overseas, they have price controls on brand medicines, and they suppress R&D, and they suppress their use, and at the same time they pay about twice as much for generics. So, instead of rewarding innovation, where the medical advances come from, they actually suppress innovation and they pay twice as much for generics.

Now generics are about 30 percent of spending on medicines in the United States. Imagine if we adopt the foreign government policies of paying twice as much for generics while pushing down on brand medicines.

Senator COLLINS. Thank you.

Mr. Romasco, just one final question. Recent studies have shown that the vast majority of Medicare Part D beneficiaries do not choose the cheapest plan, the least expensive plan, to meet their needs. And one study found that, on average, beneficiaries spend \$368 more each year than they would have spent had they purchased the least expensive plan available in their region, given their medication needs. There has been a little bit of allusion to this today.

But I want to ask you; based on your experience as the President of AARP, why do you think that is?

Mr. ROMASCO. I think we alluded to it earlier today. Dr. Woerner basically gave us an insight into the complexity and the overwhelming—when we are faced with cajillions of choices, the human reaction is to avoid and stick with what you know.

Senator COLLINS. But what those surveys show is that about 40 percent of the beneficiaries think that there are too many—

Mr. ROMASCO. Right.

Senator COLLINS [continuing]. Choices and it is confusing, but 40 percent, the other 40 percent, think it is great and like having all those choices.

Mr. ROMASCO. Well—and I think the issue is, do we have the tools in place to help people make those choices?

Some of the suggestions that Dr. Smith and Dr. Hoadley made plus, as I recall, I think you and Senator Nelson authorized a GAO study—

Senator COLLINS. We have. That was going to be in my statement.

Mr. ROMASCO [continuing]. To figure out, are these tools working?

And I think we heartily support and endorse that because that is another aspect of helping people make these choices.

Simplification and transparency—the transparency is one thing, but if it is too confusing to people, it is hard for them to make the right choices.

And the second thing is give them the right tools so when they engage it actually does benefit them.

So we heavily endorse your effort to get to the bottom of that with that GAO study.

The CHAIRMAN. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

I want to go back to the cost question that you raised, but you were talking about the cost to the government about Medicare Part D. I want to talk again about out-of-pocket costs to the individual consumer.

Back on this question about getting people to take their prescriptions and if they do not have their prescriptions filled and if they do not have them filled in a timely manner—so every 30 days on a 30-day prescription—then obviously they cannot get the benefits from those prescriptions.

I understand there is a Rand study out now that shows that for every \$10 increase in the co-pay on a prescription that compliance rates on taking medications dropped by about 5 percent. And we talked earlier about the importance of people taking those prescriptions if we are going to drive down costs and get good outcomes.

Of course, this is, in my view, one of the best parts about the Affordable Care Act—is to close the donut hole so that we get more people filling their prescriptions.

And I understand the CBO says they believe that just closing the donut hole is going to increase drug compliance—people taking their prescriptions—by about 5 percent and that is going to save us about \$35 billion.

So these are very important about how we lower costs, and so I want to go back to this question about how we lower out-of-pocket costs for our consumers—how people can get those costs down.

So, Mr. Romasco, go back to this question. What should we be doing?

Mr. ROMASCO. Well, I think, you know, I have touched on a couple of things that we think will have a significant impact on reigning in these costs. Again, secretarial negotiating authority and the biologic window for closing that exclusivity on generics for biologic and biosimilars, I think are two possible avenues.

A lot of the compliance issue—we talked about synchronization. If you look at the Affordable Care Act, the implementation of accountable care organizations begins to look at team approaches as opposed to silo approaches for patient care and the coordination of care, which allows people to both get the support of not only their physician but of their team of medical professionals, to focus on keeping the costs down and looking at the whole patient and all the dimensions of that.

Senator WARREN. I appreciate that point because it really goes back to the point that Senator Nelson was making earlier. This is not just about the out-of-pocket costs of the drugs, and it is not just about what the government spends on the drugs initially. It is to

the extent that it causes people not to have their prescriptions filled, that it increases costs on down the line. And so we are talking about a much larger impact of how the drugs are actually priced and the out-of-pocket part on that.

Mr. Smith, I will give you one more chance to say something about how we are going to bring those costs down.

Mr. SMITH. Sure. So I think that—look, I have already made my points about some of the issues that Mr. Romasco made, and I will just remind everyone because he has referenced the biologics a few times, and data exclusivity. I actually think that the one provision of the Affordable Care Act that was passed with strong recorded bipartisan majorities in both chambers was the 12 years of data exclusivity as a balance between incenting the innovation that we all want to see and creating a biosimilar pathway for affordability.

We are closing the coverage gap, and I would note that—let me take it outside of Part D for a moment, just as an example.

I would note that there are a number of employers, for instance, who—looking at how to bring down their costs—have actually cut their co-pays for medicines. And they did not do it just for generics. They did it for generics, and they did it for brands because, as Senator Wyden pointed out, people are different and need different treatments. Some are going to need a brand medicine. Others are going to be using a generic.

And they are finding that they are having a good experience by actually reducing their co-pays, and it is helping them control costs.

The final point I will make is that the co-pay is not—you know, medicines are about 10 percent of Medicare spending. Brand medicines—if you look at all Federal Medicare and Medicaid spending, brand medicines are about 8 percent of all of that spending.

So I do not think that the kinds of proposals that have been suggested are what is really going to help improve adherence. I think it is some creativity, looking at how we tie medication therapy management to utilization and looking for opportunities to take advantage of the cost savings that medicines can bring.

Senator WARREN. Fair enough, Mr. Smith.

Mr. SMITH. Yes.

Senator WARREN. But, surely, you are not pushing back on the point in the Rand study, that a \$10 increase in co-pay—

Mr. SMITH. No, no, no.

Senator WARREN. Okay, I just want to make sure that you were not saying—

Mr. SMITH. If I—

Senator WARREN. I may have misunderstood.

Mr. SMITH. Okay.

Senator WARREN. So long as we are clear on that.

Mr. SMITH. Yes.

Senator WARREN. Okay, Dr. Hoadley, did you want to add anything on that?

Mr. HOADLEY. Yes, I think you raise a really important point with the Rand study.

We have also done our own project—research project—and published an article on generic co-pays and how the use of a zero co-

pay for a generic drug can really increase utilization of that drug and adherence to that drug.

And, as Mr. Smith said, some of the flexibility that has been tried in private plans with value-based insurance design and lowering co-pays—the problem with doing that in Medicare is two-fold.

One is the basic design of Part D includes 25 percent average cost-sharing. So a plan that wants to lower their co-pays overall has to do it as an enhanced plan with a higher premium, and that is one approach, or there has got to be some change in the legislation in terms of the overall average cost-sharing level and bringing it down lower than 25 percent. Obviously, there are implications for doing that.

But, even with that, perhaps some greater flexibility that CMS could look at, in terms of letting plans experiment with lower co-pays for certain classes of drugs that are really much more important clinically, is something to think about but, also, certainly trying to push plans and encourage plans to look at lower co-pays for generics where you can get more bang for the buck.

The last comment I would make is one of the things that really complicates the story for the Part D program is that in the world of standalone drug plans, if we increase adherence, we are actually increasing the amount of spending that the plans are on the hook for.

And so, we have built in kind of a perverse incentive to say they are going to do better when less spending occurs on the drugs, whereas, in fact, we may want more spending on drugs to get the higher occurrence, to get the payoff in Part A and Part B. So figuring out a way to change and rethink about how we build the standalone drug plans, to get away from that perverse incentive, is something really worth trying to think about.

Senator WARREN. That is a very good point.

And, Dr. Woerner, did you want to add anything to this?

I am over time, so I will ask you to be brief.

Ms. WOERNER. Only that I think by simplifying the process of choosing a plan it would help individuals find plans in which their costs would be lower. That is a minor thing, but it is something that could be done.

Senator WARREN. I do not see that as minor. I take it to be a good point.

But I do understand that if we are trying to reduce costs overall, co-pay costs for the individual must come down, and that we are just caught in the wrong cycle right now with high co-pays. We have got to change that if we are going to have better outcomes at lower costs.

Good. Thank you all.

Thank you, Mr. Chairman. Thank you very much for doing this.

The CHAIRMAN. Well, going to the broader issue, from drug plans to the Medicare Advantage plans, there is a Star Rating System. The idea is that you let the competitive market forces work—a senior sees that this insurance Medicare plan is rated higher on quality and that they would vote with their feet and they would go to the higher rated one.

Now it has just been in existence for—just beginning.

Do you all have any comment on the Star Rating System?

Mr. HOADLEY. The Star Rating System has been around. I mean the new financial incentives that are attached to it are the newest part of that, but we have had Star Ratings now really since almost the beginning of Part D.

What we do not understand very well is the degree to which consumers are using those ratings to make choices of drug plans.

The information is out there. It is on the web site, so it is very accessible. And we think we have done it in a reasonably comprehensible way. But we have not seen a lot of research yet to know how much people are using that information.

When we look in the aggregate at how many people are in plans with different kinds of Star Ratings, we do not see a particularly higher enrollment in the 5-Star or 4-Star rated plans over the 3-Star rated plans.

So I think more transparency and more publicity to those ratings but, also, more research to sort of see what is it that people take into account.

And this whole phenomenon of simplifying the program—you know, to the extent that people just are not even shopping, then obviously, they are not shopping based on stars. If they say this is too complicated, I am going to stick in the plan I am in even though it has a 2.5-Star Rating and even though it has gotten more expensive within the last 3 years, that is where the problem lies.

So finding ways to encourage people, to make it easy to shop, and then to take into account some of the ratings as well as the direct cost factors is something that we need to do better at.

Mr. SMITH. Senator, if I might, one of the important aspects of the Star Rating System is, in fact, adherence to medicines. It gets a pretty good weighting in the Star System. I think that that is important. It is a good incentive.

And let me just add to Dr. Hoadley's comments that I think we have to recognize that some of this is going to be a work in progress.

And there was discussion about the importance of beneficiaries shopping among plans, and I think that is absolutely right. Beneficiaries, when they do switch plans, they save money on their out-of-pocket costs. That is really important—an average of about \$300.

One of the things that MedPAC has found is that in the early years of the program we only had about 6 percent of beneficiaries who were switching plans at open enrollment. That is now ticked up according to MedPAC's finding to, I believe, 13 percent. And among some of the younger enrollees coming in—the younger cohort coming into the program—it is even a little higher; it is about 16 percent.

So I think that there are opportunities. We want to encourage people to shop. We want to give them those tools. And that can help. It can help on the quality side. It can help on the out-of-pocket cost side because when they do switch they are saving money.

The CHAIRMAN. How much, in your opinion, is the lowered cost that we are seeing due to the utilization of generics?

Mr. HOADLEY. It is really a very large factor in what has driven. And the study that I did, published last year, looked at the generic use as being one of the very important factors in the lower cost trends.

We have had such a swing in the period of time since 2006, when the first enrollment in Part D occurred, to more generic use. And I think the numbers just between 2006 and 2010 were something like 60-some percent generic use up to 80 percent generic use, and it is undoubtedly higher since 2010 per the most recent data I have seen.

So I do think that has been a very big part of the story, but it could be even more.

Mr. SMITH. If I might, I am going to agree that use of generics is a sizeable part of the savings, but two points about that that I touched on in my testimony.

One is those generics originated with innovator medicines. They would not have been there if there were not innovator medicines to copy and that have been developed.

And the second is that it is really our marketplace that drives the very high use of generics and maximizes the savings out of them. Mark McClellan, when he was CMS Administrator at the early days of the program, emphasized that Part D and its competitive forces are actually driving up generic use.

The CHAIRMAN. But you are happy with the health care bill that gave 12 years exclusivity for the biologics?

Mr. SMITH. We fully agree with the determination made in Congress, absolutely.

The CHAIRMAN. You brought out here in this hearing that the low-income subsidy assistance is not being utilized like it should. What can we do?

Mr. HOADLEY. I think it is a hard thing to address. I think some of it is the, again, complexity. So there is an Asset Test attached to the low-income subsidy eligibility unless people come in through their Medicaid programs in some states.

And so there is some thought that the fact you have to not only meet an income test but you have also got to attest to your assets is something that some people just do not want to go through. They do not want to do that additional paperwork. It makes the forms longer and more complicated.

We do not understand this question very well, and that is one of the dilemmas, but I think that it is probably one of the sources—the fact that you have to go through an application process. You have to submit an application either to the state Medicaid agency or to the Social Security Administration; fill out an application; wait and get that approved. That is also certainly a factor.

And then I think some of it is just knowledge. I think Dr. Woerner talked about people who were not aware that there were these subsidies available. And we just need to do a better job of building awareness about the existence of the subsidies so that people know that they have that option available.

The CHAIRMAN. I will wrap up if it is okay with you all.

You mentioned, Senator Warren, the burdensome cost to seniors, and I had mentioned the excess cost to the U.S. Government in trying to afford the prescription drug benefit.

The Inspector General has come out with a study that says that Medicaid as compared to Medicare with regard to drugs—that Medicaid collected two-thirds as much in rebates as Medicare Part

D despite having only one-quarter of the expenditures that Medicare has in their drugs.

And the most shocking part about this finding is that the IG did this study with data before the Affordable Care Act mandated the Medicaid rebate percentage increase taking effect. So this is before all of that occurred. There was still this huge disparity.

It is a disparity, for example—and we will have copies of this chart if you need it—that shows on Prevacid for heartburn and acid reflux, Medicaid paid 65 percent less than what Medicare paid; with Crestor, to lowering cholesterol, that Medicaid paid 42 percent less than Medicare, and so forth.

Now that is in the IG study done back then.

So I am going to call for the IG to have another study to get the latest information on these numbers, and then we can discuss that at a future hearing.

Any further comments?

Okay. Well, thank you all. You have been an excellent panel. The meeting is adjourned.

[The prepared statements for the record are in the Appendix]  
[Whereupon, at 4:09 p.m., the Committee was adjourned.]



## **APPENDIX**



### Statement for the Record

United States Senate Special Committee on Aging Hearing  
*10 Years Later: A Look at the Medicare Prescription Drug Program*  
 Wednesday, May 22, 2013

Mr. Chairman and Members of the Committee:

I am Max Richtman, President and Chief Executive Officer of the National Committee to Preserve Social Security and Medicare (NCPSSM). I appreciate the opportunity to submit a statement for the record to the Special Committee on Aging for the hearing, *10 Years Later: A Look at the Medicare Prescription Drug Program*. My comments today focus on recommendations for improving the Medicare Part D program.

The Medicare Prescription Drug Program, established under the *Medicare Modernization Act of 2003*, has provided millions of older Americans with access to affordable drug coverage that they previously did not have. In 2012, over 30 million Medicare beneficiaries enrolled in a Part D plan. The National Committee is pleased that the Medicare Part D program is continuing to evolve. In recent years, beneficiary premiums have remained stable and, by 2020, the Part D “donut hole” will be closed because of the *Affordable Care Act*.

However, the National Committee believes that further improvements to Medicare Part D are needed to reign in drug costs and better serve beneficiaries. This is important because many older Americans struggle to pay for their health care premiums, deductibles and co-payments. In 2012, over half of Medicare beneficiaries had incomes below \$22,500. These individuals are paying, on average, about 26 percent of their Social Security check to cover Part B and D premiums and cost sharing, in addition to paying for health services not covered by Medicare. Because of their lower average household budgets and higher average health care spending, families on Medicare spend 15 percent of their household budgets on health care, which is three times more than what non-Medicare households spend on health care.

The National Committee supports the following improvements to Medicare Part D, which can be made without shifting costs to beneficiaries: 1) Restoring drug rebates for low-income Medicare beneficiaries, 2) Improving access to the Part D Low-Income Subsidy (LIS) and 3) Increasing access to generic and biologic drugs.

#### *1) Restoring Drug Rebates for Low-Income Medicare Beneficiaries*

Prior to the implementation of Medicare Part D in 2006, drug companies paid the government rebates for drugs used by beneficiaries who are dually eligible for Medicare and Medicaid. Legislation introduced in the 113<sup>th</sup> Congress by Senator Jay Rockefeller and Representative Henry Waxman, the *Medicare Drug Savings Act* (S. 740, H.R. 1588), would restore these rebates. They would require drug manufacturers to pay rebates for the drugs used by individuals who are dually eligible for both Medicare and Medicaid and receive the Part D low-income subsidy. The Congressional Budget Office estimates that the *Medicare Drug Savings Act* would save \$141 billion over 10 years. The National Committee supports this legislation because it would produce significant savings to Medicare without cutting benefits.

*2) Improving Access to the Part D Low-Income Subsidy (LIS)*

The Medicare Part D Low-income Subsidy (LIS), also known as *Extra Help*, provides assistance to low-income beneficiaries who are enrolled in Part D with their out-of-pocket prescription drug expenses. The amount of the assistance depends on beneficiaries' income and assets. In 2013, annual income is limited to \$17,235 and assets to \$13,300 for LIS eligibility for an individual. The Social Security Administration estimates that the annual value of the LIS benefit is about \$4,000 a year. Despite these savings, more than two million low-income beneficiaries eligible for the LIS did not enroll in the program. Reasons for low participation include unawareness of the LIS program, cognitive impairment, lack of basic math skills and/or an inability to meet the asset test.

The National Committee believes that low-income individuals who are eligible to receive extra financial assistance for their prescription drug costs should receive it. Therefore, we support providing additional funding for community-based outreach and enrollment efforts to educate and assist low-income individuals with enrollment. These efforts should provide special attention to assisting populations that are hard to reach, such as those with cognitive impairments or have language access issues. We also support raising the LIS asset test limit because low-income seniors who have accumulated modest assets should not be punished for trying to save for retirement. We urge Congress to examine whether the LIS asset test is denying access to low-income Part D beneficiaries.

*3) Increasing Access to Generic and Biologic Drugs*

Some brand name drug manufacturers pay generic drug manufacturers to keep less expensive generic drugs off the market for a certain period. The National Committee opposes these "pay-for-delay" agreements because greater use of generic drugs would lower Medicare costs. The Congressional Budget Office found that the use of generics saved Medicare \$33 billion in 2007. The National Committee supports the President's Fiscal Year 2014 Budget proposal that would increase the availability of generic drugs and biologics (drugs made from living organisms and their products) by authorizing the Federal Trade Commission to stop companies from entering into "pay for delay" agreements, which would prevent consumers from receiving access to safe and effective generics. This proposal would save \$11 billion over 10 years.

We also support the President's proposal to accelerate access to affordable generic biologics by modifying the length of exclusivity on brand-name biologics. Beginning in 2014, this proposal would award brand biologic manufacturers seven years of exclusivity, rather than 12 years under current law, and prohibit additional periods of exclusivity for brand biologics due to minor changes in product formulations. This proposal would create \$3 billion in savings over 10 years.

In brief, the National Committee urges Congress to consider additional improvements to Medicare Part D, such as the proposals noted, to serve beneficiaries better and lower health care costs. We believe that enhancements can be made to Part D without shifting costs to beneficiaries, especially those with low-income.

Thank you for the opportunity to submit a statement for the record expressing our views.



Statement  
Of  
The National Association of Chain Drug Stores  
For  
U.S. Senate  
Special Committee on Aging  
Hearing on:  
10 Years Later: A Look at the  
Medicare Prescription Drug Program

May 22, 2013  
2:30 p.m.  
366 Dirksen Building

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*NACDS Senate Special Committee on Aging  
10 Years Later: A Look at the Medicare Prescription Drug Program  
May 22, 2013  
Page 2 of 5*

The National Association of Chain Drug Stores (NACDS) thanks the Members of the Special Committee on Aging for consideration of our statement for the hearing on “10 Years Later: A Look at the Medicare Prescription Drug Program.” NACDS and the chain pharmacy industry are committed to partnering with Congress, the Centers for Medicare & Medicaid Services, patients, and other healthcare providers to improve the quality and affordability of the Medicare program.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The majority of Medicare Part D prescriptions are dispensed by chain pharmacies.

As the face of neighborhood healthcare, community pharmacies and pharmacists provide access to prescription medications and over the counter products, as well as cost-effective health services such as immunizations and disease screenings. Through personal interactions with patients, face-to-face consultations and convenient access to preventive care services, local pharmacists are helping to shape the healthcare delivery system of tomorrow – in partnership with doctors, nurses and others.

In recent years retail community pharmacies have played an increasingly important role in providing patient care. Activities such as the increased number of health screenings provided by pharmacists help educate patients and give them a better understanding of their health status and potential needs. Pharmacists also provide vital patient care through services such as medication therapy management (MTM) and their expanded role in providing immunizations.

Congress recognized the importance of MTM, including it as a required offering in the Medicare Part D program. The experiences of Part D beneficiaries, as well as public and private studies, have confirmed the effectiveness of pharmacist-provided MTM.

A recent report by CMS found that Medicare Part D beneficiaries with congestive heart failure and COPD who were newly enrolled in the Part D MTM program experienced increased medication adherence and discontinuation of high-risk medications. The report also found that monthly prescription drug costs for these beneficiaries were lowered by approximately \$4 to \$6 per month and that they had nearly \$400 to \$500 lower overall hospitalization costs than those who did not participate in the Part D MTM program.

How and where MTM services are provided also impacts effectiveness. A study published in the January 2012 edition of *Health Affairs* identified the key role of retail pharmacies in providing MTM services. The study found that a pharmacy-based intervention program increased patient adherence for patients with diabetes and that the benefits were greater for those who received counseling in a retail, face-to-face setting as opposed to a phone call from a mail order pharmacist. The study suggested that interventions such as in-person, face-to-face interaction between the retail pharmacist and the patient contributed to improved behavior with a return on investment of 3 to 1.

Similarly, policymakers have begun to recognize the vital role that local pharmacists can play in improving medication adherence. The role of appropriate medication use in lowering healthcare costs was recently acknowledged by the Congressional Budget Office (CBO). The CBO revised its methodology for scoring proposals related to Medicare Part D and found that for each one percent increase in the number of prescriptions filled by beneficiaries there is a corresponding decrease in overall Medicare medical spending. When projected to the entire population, this translates into a savings of \$1.7 billion in overall healthcare costs, or a savings of \$5.76 for every person in the U.S. for every one percent increase in the number of prescriptions filled.

Congress recognized the importance of MTM on a bipartisan basis, including it as a required offering in the Medicare Part D program. We urge Congress to build on this earlier action, and strengthen the MTM benefit in Medicare Part D through support of *the Medication Therapy Management Empowerment Act of 2013*, S. 557 sponsored by Sen. Kay Hagan (D-NC) (House companion legislation H.R. 1024). This important legislation would improve access to MTM

services for Medicare Part D beneficiaries leading to increased healthcare quality and reduced overall healthcare costs. Under the legislation, Medicare Part D beneficiaries who suffer from one, rather than multiple, chronic diseases that account for high spending in the Medicare program would be eligible for MTM services. We urge members to co-sponsor S. 557.

Additionally, NACDS believes the choice of where to obtain prescription drugs and pharmacy services should be left to Medicare beneficiaries. In order to make an informed choice, it is important for beneficiaries to have clear information. According to a Medicare Payment Advisory Committee (MedPAC) report, approximately 12.5 percent of Medicare beneficiaries were enrolled in a Prescription Drug Plan (PDP), and three percent in a Medicare Advantage Plan with a preferred network design. Participation in preferred networks is increasing.

We applaud efforts by CMS to ensure beneficiaries are fully educated when making plan selections and do not make selections based on ambiguous information. NACDS recommends that all beneficiaries be given clear instructions that, regardless of plan selection, they still retain the right to have a prescription filled at the pharmacy of their choosing and are not required to obtain their prescriptions at a preferred network. Ensuring beneficiary awareness of this policy will lead to less confusion and will allow beneficiaries to continue to utilize the pharmacy of their choice.

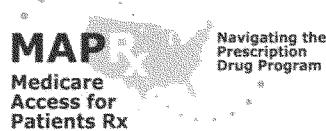
While beneficiary cost sharing may encourage the use of a preferred pharmacy, it should not be so significant as to disadvantage Medicare beneficiaries who rely on a pharmacy not in the preferred network. This may be particularly important in rural and urban areas, where beneficiaries may have to travel long distances or have difficulties accessing preferred network pharmacies. Additionally, as more beneficiaries use preferred networks, and because many seniors may have both financial and physical limitations which prevent them from being able to travel to a preferred pharmacy, preferred networks should be monitored to ensure that beneficiary needs are adequately met and that quality of care is not compromised.

Despite the proven effectiveness of pharmacists in delivering preventive services such as immunizations and MTM, limitations remain in place that prevent pharmacists from practicing to

the maximum of their capabilities. These limitations have prevented local retail pharmacists from participating in the various new innovative programs, such as those being supported by the Center for Medicare and Medication Innovation (Innovation Center). These include the new Accountable Care Organization Models, community-based transitions of care, and bundled payment initiatives.

Permitting pharmacists to practice to their maximum capabilities within these new delivery models would help increase medication adherence and coordination between healthcare settings, result in higher rates of vaccinations, and reduce the burden of the physician shortage, particularly with the influx of new patients in 2014 through the Healthcare Marketplaces and the expansion of Medicaid eligibility. As we move forward with the reform of the healthcare delivery system and improving Medicare, it is imperative for all healthcare providers to practice to their maximum capabilities, working in partnership to provide accessible, high quality care to patients.

Thank you for the opportunity to share our views. We look forward to continuing to work with the committee to advance policies that improve care for Medicare beneficiaries.



### MAPRx Coalition Principles for Prescription Drug Benefit Design

The Medicare Prescription Drug Benefit Program (Medicare Part D) is a critical lifeline to millions of Medicare beneficiaries by providing access to prescription drugs. The Medicare Access for Patients-Rx Coalition (MAPRx), a coalition of 45 national patient, family, caregiver and health professional organizations, was instrumental in helping the Centers for Medicare and Medicaid Services (CMS) design a Part D benefit that improved access to prescription drugs under Medicare, while also providing significant patient protections for beneficiaries with chronic diseases and disabilities.

#### **Medicare Part D and Prescription Drug Benefit Design**

Prescription drugs improve health outcomes and save money, when used as directed<sup>i</sup>. Researchers found that implementation of the Medicare prescription drug program was followed by a decrease of more than \$1,200 in nondrug medical spending among those who previously had limited drug coverage.<sup>ii</sup>

While not perfect, Part D's success and popularity suggests that the program is working well for many Medicare beneficiaries. As we enter a new era of healthcare, it is imperative that policymakers and key stakeholders work together to design prescription drug benefit programs that meet the needs of people with chronic diseases and disabilities.

**MAPRx urges policymakers to learn from the experience with Medicare Part D - build on its successes and improve on its limitations.** To that end, we encourage the use of the following principles to guide the design of prescription benefit programs. We also encourage policymakers to improve on the limitations of Part D.

- **Plans should be required to have a robust formulary and provide coverage for a variety of medications in each drug class or category.**
- **Coverage should be required for Medicare Part D's six protected classes of drugs and any additional classes where restricted access to those drugs would have significant health consequences.**
- **Oversight of a prescription drug benefit should include monitoring of: plan operations, formulary design, plans' use of utilization management tools, quality measures, and pharmacy and therapeutic (P&T) committees.**
- **Plans should be required to provide clarity and transparency on coverage and on consumer's out-of-pocket costs.**
- **Notice of non-coverage, appeals and exceptions process should be simple and understandable.**
- **Rigorous oversight of medication utilization management tools (such as medication substitution, step therapy or quantity limits) is critical to patients' timely access to prescription drugs.**

*The principles and a discussion of some Medicare Part D's limitations are discussed in detail below.*

#### **The Principles**

- I. Plans should be required to have a robust formulary and provide coverage for a variety of medications in each drug class or category.**
- II. Coverage should be required for Medicare Part D's six protected classes of drugs and any additional classes where restricted access to those drugs would have significant health consequences.**
- III. Oversight of a prescription drug benefit should include monitoring of:**
  - **Plan operations** with an emphasis on key performance measures such as frequency and types of complaints, timeliness and resolution of appeals, completeness of enrollment information accessible to pharmacists, and availability of changes to drug pricing;
  - **Formulary design** to determine that appropriate access is afforded to physician prescribed treatments and to ensure that the formulary does not discriminate or discourage enrollment by certain beneficiaries;
  - **Plans' use of utilization management tools** such as prior authorization, quantity limits and step therapy (where a lower cost drug is tried first before a higher cost drug may be used), should be required to meet best practice standards and appropriate treatment guidelines;
  - **Quality measures** should be meaningful to help beneficiaries make an informed drug plan choice and provide CMS necessary information in its oversight role. Measures should include customer service, access to needed drugs, appeal and denial rates, beneficiary protections and overall satisfaction; and,
  - **Pharmacy and therapeutic (P&T) committee membership, including robust consumer representation, as well as process and procedural requirements** should ensure access to medically necessary medications. These requirements should include procedural safeguards and timely review of every newly FDA-approved drug so that beneficiaries do not encounter barriers, such as potentially long and unnecessary delays, that hinder their access to medication therapies.
- IV. Plans should be required to provide clarity and transparency on coverage and on consumer's out-of-pocket costs.** A mix of co-payments and coinsurance can cause significant confusion especially for individuals on multiple and/or expensive medications trying to navigate the system and compare plans. The ability to understand the benefits provided in a plan, along with coverage levels and out-of-pocket costs is an important factor for consumers when making a determination of which plan best meets their needs.
- V. Notice of non-coverage, appeals and exceptions process should be simple and understandable.** Enrollees should be given timely notice of the reasons for the denial of drug coverage and their appeal rights, including the right to an expedited review. Regulatory oversight should ensure sufficient consistency in exceptions processes among all plans so that providers can assist beneficiaries in an efficient and effective manner.

**VI. Rigorous oversight of medication utilization management tools (such as medication substitution, step therapy or quantity limits) is critical.**

- Insurers should not be allowed to override a health care provider's practice of medicine by forcing utilization of certain medications or therapies that may be inappropriate to the care of their patients.
- Plans should provide information and transparency about their utilization management tools, including notice of plan changes and the right to appeal.
- Plans should provide clear, relevant patient information on the use of utilization management tools prior to enrollment.

**Limitations of Medicare Part D**

Medicare Part D is by no means perfect - key limitations prevent beneficiaries from taking full advantage of the benefits of prescription drug therapy. Policymakers should understand the limitations of Part D and not replicate them:

- I. **Prohibit gaps in coverage**, as they result in beneficiaries modifying their drug use by stopping or reducing their use of certain medications. From 2006, when the Medicare Part D drug benefit took effect, to 2011, beneficiaries were required to pay 100 percent of their drug costs after their total drug spending exceeded an initial coverage limit until they qualified for catastrophic coverage. Researchers have found some beneficiaries discontinue their drug therapy during the coverage gap<sup>iii</sup>. Fortunately, the *Affordable Care Act* closes this coverage gap by 2020.
- II. **Avoid Onerous Cost-Shifting onto Beneficiaries**. Many Medicare prescription drug plans have added to their formulary a "specialty tier" for high-cost medications. Unlike lower cost medications, for which beneficiaries usually pay a set co-pay amount, these medications are subject to significant coinsurance, meaning that beneficiaries must pay a percentage of the medication's cost. For drugs in the specialty tiers, this amount can be anywhere from 25-33%, leaving patients to pay thousands of dollars out-of-pocket for cost prohibitive drugs and biologics used to treat cancer, multiple sclerosis, hemophilia, lupus, rheumatoid arthritis, and other conditions. For many beneficiaries, the result is that they are denied access to the most appropriate, useful medication due to the fact that it is financially out of reach. For those who can afford the drugs, they pay enormous sums out of pocket to maintain their health.
- III. **Curb the Use of Restrictive Medication Utilization Management**. Many Part D plans now employ medication utilization management tools, such as prior authorization, medication substitution or quantity limits that restrict a beneficiary's access to drugs. For example, a "fail first" policy requires that beneficiaries prescribed an expensive medication must first use a less expensive or plan preferred medication, experience that medication failure first before the plan will pay for the original prescription. These policies place unnecessary barriers to patients' access to the medications recommended by their physicians. For many health conditions, such policies threaten patients' lives, safety and medical stability.
- IV. **Improve program effectiveness, including access, for beneficiaries eligible for low-income subsidies**. Medicare makes additional payments to plan on behalf of beneficiaries entitled to subsidies due to low income and asset levels (often referred to as "LIS beneficiaries.") The asset test is a particular barrier for many low-income beneficiaries who need help paying for coverage. Despite outreach efforts, not all eligible beneficiaries have enrolled. In addition, a large number of beneficiaries are required to change plans each year because the premium for their current plan no longer falls below the low-income subsidy level. Changing plans can cause disruption to continuity of care.

- V. **Improve beneficiary education, decision-making and assistance for choosing the Part D plan best for them.** Beneficiaries need to be well informed and compare options in order to make the market work well. However, a June 2012 report from the National Bureau of Economic Research found that fewer than 10 percent of individuals enrolled in what would be for them the most cost-effective Part D plan.<sup>v</sup> More needs to be done to encourage beneficiaries to shop around and to provide beneficiaries with the tools and support needed to make well-informed decisions. In its March 2012 Report, MedPAC states that only about 6 percent of beneficiaries switched plans voluntarily.<sup>v</sup>

#### **About MAPRx**

Founded in 2005, MAPRx brings together 45 national patient, family, caregiver and health professional organizations committed to protecting the health and well-being of individuals with chronic diseases and disabilities by improving access to affordable prescription drugs through the Medicare Part D Program and private insurance market. MAPRx members work collaboratively to advocate and advance federal legislation and public policies that ensure access to affordable prescription drugs while helping people with chronic diseases and disabilities maintain their health, well-being and financial security. The Coalition works diligently to ensure that Medicare beneficiaries have access to prescription drugs and receive timely and accurate information about their Part D benefit, helping them make informed decisions about their care and treatment options.

**For additional information on MAPRx and the Coalition Principles, contact Bonnie Hogue Duffy, MAPRx Coalition Convener, at [Bonnie@maprxinfo.org](mailto:Bonnie@maprxinfo.org) or (202) 429-4017.**

<sup>v</sup>Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication adherence leads to lower health care use and costs despite increased drug spending. *Health Affairs* 2011;30(1):91-99. This study was done in patients with congestive heart failure (CHF), hypertension (HTN), diabetes (DM), and dyslipidemia to determine the effects of adherence on patient outcomes, both economically and clinically. The study determined that the average number of days spent in inpatient settings was reduced from 1.18-5.72 days annually, and despite higher spending on medication, total healthcare savings ranged from \$1,258 - \$7,823 when patients were adherent.

<sup>vi</sup> J.M. McWilliams et al. "Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage," *Journal of the American Medical Association*, 27 July 2011. Total nondrug medical spending after the implementation of Part D was significantly lower (-\$306/quarter [95% confidence interval (CI), -\$586 to -\$51];  $P = .02$ ) for beneficiaries with limited prior drug coverage and for those beneficiaries with generous prior drug coverage.

<sup>vii</sup> Yuting Zhang, et al. The Effects of the Coverage Gap on Drug Spending: A Closer Look at Medicare Part D. *Health Affairs*, March April 2009. Those lacking coverage in the donut hole reduced their drug use by 14 percent; those with generic coverage reduced their use by 3 percent.

<sup>viii</sup> Heiss, Florian, Leive, Adam, McFadden, Daniel, Winter, Joachim; Plan Selection in Medicare Part D: Evidence from Administrative Data, June 2012; Working Paper 18166; National Bureau of Economic Research.

<sup>v</sup> MedPAC Report to Congress: Medicare Payment Policy, March 2012. Based on most recent data from the early years of the program.



**Statement for the Record**

**for the**

**UNITED STATES SENATE  
COMMITTEE ON AGING**

**Hearing on**

**“10 Years Later: A Look at the Medicare Prescription Drug Benefit”**

**May 22, 2013**

## **Introduction**

The Pharmaceutical Care Management Association (PCMA) appreciates this opportunity to submit our statement for the record of the May 22, 2013 Senate Committee on Aging Hearing on “10 Years Later: A Look at the Medicare Prescription Drug Benefit.” PCMA is the national association representing America’s pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 216 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP).

PBMs utilize a number of tools and strategies to manage prescription drug benefits that maximize value for health plan enrollees and PBM clients – employers, health plans, federal and state governments, and other payers. A common thread connecting all programs administered by PBMs is that success depends on offering the best overall value in terms of cost, quality, access, and convenience for health plan enrollees as well as saving PBM clients money. To stay in business, PBMs must deliver high-quality prescription drug benefits at highly competitive prices.

## **PBMs Assure the Success of Medicare Part D**

The Medicare Prescription Drug benefit program does not negotiate prescription drug prices or discounts directly with manufacturers or pharmacies, but instead relies on Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs), and their PBMs, to negotiate price concessions for covered prescription drugs and reduce wasteful spending. Through rulemaking, sub-regulatory guidance, and an annual call letter, CMS establishes the parameters within which participating MA-PDs and PDPs must operate. This process encourages plans to innovate and implement new initiatives that address rising drug costs and encourage appropriate drug usage.

Negotiating price concessions on drugs is just one of the many ways PBMs reduce pharmacy benefit costs. PBMs encourage higher generic utilization, employ more affordable delivery options such as mail-service pharmacy, negotiate discounts from retail pharmacies, and help doctors and patients understand when safer, more affordable options are available. PBMs understand that the “unit price” of a drug is only one of many different components of prescription drug spending.

PBMs also have introduced important new advances to improve safety and clinical appropriateness in the Medicare Part D program. Specifically, Part D plans:

- Use sophisticated Drug Utilization Review (DUR) programs to improve drug safety and prevent fraud;
- Offer Medication Therapy Management (MTM) programs to improve safety for seniors who take multiple prescriptions for chronic conditions; and
- Provide broad access to thousands of prescription medications through an array of benefit designs, enabling beneficiaries to select a plan that best meets their medical and economic needs.

These methods have proven successful in lowering the overall increases in the costs of drugs. According to the CMS National Health Expenditures Accounts, annual expenditures on outpatient prescription drugs have increased more slowly in the past four years than at any time in the previous four decades. In 2011, expenditures on prescriptions increased just 2.9 percent, well below the 3.9 percent rate of increase in health expenditures overall.

This trend is due in large part to a continued increase in generic dispensing from 67 percent of prescriptions in 2007 to 80 percent in 2011. PBMs have been a driving force of this trend, encouraging generic utilization through lower or waived copayments and formulary compliance programs such as step therapy. Generic dispensing rates are generally higher in plans administered by PBMs, including Part D plans, than in other federal or state programs that do not avail themselves of PBM drug management services, especially Medicaid. This is significant, because every one percentage point increase in the generic fill rate can translate into a one percentage point reduction in drug costs.

Medicare Part D relies on competition, not price controls, and has consistently performed better than CBO projections:

- Part D currently operates at more than 40 percent below initial budget projections;
- Part D has achieved beneficiary satisfaction rates close to 95 percent; and
- Part D had a low 2.9 percent annual growth rate in per capita spending from 2006 to 2010, according to the recent MedPAC report.

#### **Potential for Significant Additional Savings in Medicare Part D**

Looking ahead to the next ten years of the Medicare Prescription Drug program, PCMA urges the Committee to consider policy changes set forth below that would enhance program efficiency and effectiveness and produce large savings for both the government and Medicare beneficiaries.

**Encourage Greater Use of Preferred Pharmacy Networks.** Preferred pharmacies offer plans better discounts than non-preferred pharmacies, and plans, in turn, lower copays and cost sharing for beneficiaries who choose to fill their prescriptions at a preferred pharmacy. For the 2013 benefit year, Medicare Part D plans with preferred pharmacy networks enrolled 9.5 million beneficiaries, which is 42 percent of all seniors enrolled in a Medicare PDP. Eighty-five percent of those enrollees are overwhelmingly satisfied with their plan, citing lower costs, convenient access to pharmacies, and other benefits according to a new survey by Hart Research Associates conducted for PCMA.

Another recent PCMA study found that greater use of preferred and limited pharmacy networks could save the Medicare program \$35 billion over the next ten years while meeting current pharmacy access standards. The savings results from competition among the abundance of pharmacies in the United States, including those in big-box stores like Target and Walmart, in grocery stores, independent and chain pharmacies, and mail-service pharmacies. Since there are over 60,000 retail pharmacies nationwide -- more than McDonalds, Burger Kings, Pizza Huts, Dunkin Donuts, Wendy's, Taco Bells, Kentucky Fried Chickens, and Domino's Pizzas *combined*

-- preferred pharmacies can save money without reducing access and convenience for beneficiaries.

**Encourage Home Delivery.** Home delivery is popular with patients with chronic conditions because it offers less expensive 90-day prescriptions and is more convenient than driving to a drugstore. Mail-service pharmacies are typically used only after a patient has been stabilized on a medication after several 30-day prescriptions have been dispensed by a local drugstore. With mail-service pharmacies, patients have access to private counseling over the phone from trained pharmacists seven days a week, 24 hours a day. In a recent letter to the United States Postmaster General, 88 members of the U.S. House of Representatives extolled the value of mail-service pharmacies, saying that "home delivery is the most cost-effective way of filling prescriptions for TRICARE beneficiaries, and saves Medicare and Medicaid money as well." Currently, enrollees in private sector retiree plans use home delivery four times more often than seniors enrolled in Part D plans because Medicare places restrictions on home delivery benefit options.

**Expedite the Approval of Biogenerics.** As the number and costs of biologic drugs increases, so does the urgency for the beginning of an approval pathway for biogeneric products. The President's budget proposes to "accelerate access to affordable generic biologics by modifying the length of exclusivity on brand name biologics. Beginning in 2014, this proposal would award brand biologic manufacturers seven years of exclusivity, rather than 12 years under current law, and prohibit additional periods of exclusivity for brand biologics due to minor changes in product formulations, a practice often referred to as 'evergreening.'" According to the budget, these changes would yield \$3 billion in savings for Medicare and Medicaid.

**Allow Plans in Medicare Part D to Negotiate Discounts on Every Brand Drug.** Congress should increase price competition among brand drug manufacturers by removing the formulary requirement that "all or substantially all" drugs be covered in six drug classes of clinical concern. While there is little evidence that this requirement improves beneficiary access to appropriate medications, it does reduce the ability of Part D plans to negotiate discounts with drug manufacturers. When manufacturers are guaranteed coverage of their drug products in Part D plan formularies, there is no incentive for them to offer price concessions. According to the Centers for Medicare and Medicaid Services, this requirement has increased Part D drug costs by \$4.2 billion since the program was enacted.

#### **Conclusion**

Medicare Part D is successful because it relies on market forces and competition to deliver high-quality benefits and services to beneficiaries. By using PBMs' management strategies proven in the commercial market, Part D plans achieve significant savings for beneficiaries in their drug benefits and provide wide access to medications and pharmacies at affordable prices. PBMs and Part D sponsors have generated more generic utilization than Medicaid and provided more choice of drugs and pharmacies than the Veterans' Administration health program. Most importantly, Medicare beneficiaries are very pleased with Part D's performance.

In Part D, PBMs have worked hard to meet the high expectations of seniors and policymakers alike. While there is always room for improvement, PBMs are proud of their performance to date. Additional savings for Part D could be obtained if CMS encouraged health plans and PDPs to adopt even greater use of preferred pharmacy networks, home delivery, formulary tiering, step therapy, prior authorization, and other utilization management tools that facilitate cost-effective medication use.

PCMA looks forward to working with the Committee and Congress to find additional ways to promote savings while continuing to deliver the highest quality and highest value prescription drug benefits for Medicare beneficiaries.

**Written Statement for the Record by Ron Pollack, Executive Director, Families  
USA**  
**United States Senate Special Committee on Aging Hearing**  
***"10 Years Later: A Look at the Medicare Prescription Drug Program"***  
**Wednesday, May 22, 2013**

Chairman Nelson, Ranking Member Collins, and members of the Senate Special Committee on Aging:

I submit this statement on behalf of Families USA, a national nonprofit, non-partisan organization dedicated to the achievement of high-quality, affordable health care for all Americans. Families USA appreciates the opportunity to submit a statement for the record to the Special Committee on Aging for the hearing, *"10 Years Later: A Look at the Medicare Prescription Drug Program."* Our comments focus on improving and preserving the Medicare Part D program by restoring drug rebates for low-income people with Medicare. Drug rebates in Medicare represent a way to find savings in Medicare without hurting low-and middle-income Medicare beneficiaries who rely on the program for their health care and affordable prescription drugs. As policymakers grapple with how to reduce the deficit, it is especially important to embrace solutions that do not put additional burdens on the most vulnerable Americans. This statement outlines why restoring drug rebates in Medicare represents good public policy that will not harm seniors' access to affordable prescription drugs.

***Medicare Drug Rebates Do Not Represent New Policy. Rebates Would Save Money***

Prior to the passage of the Medicare Modernization Act of 2003 (MMA) which established the Medicare Prescription Drug Program, the federal government received rebates from pharmaceutical manufacturers for drugs provided to people who were eligible for both Medicare and Medicaid. Applying Medicaid-level rebates to Medicare drugs would simply restore a practice that existed for dually eligible beneficiaries prior to the passage of MMA. Furthermore, drug rebates are the current policy in the Medicaid program and are proven to save money. For example, a recent Department of Health and Human Services Office of Inspector General report found that the federal government benefits from drug rebates in the Medicaid program. This report compared 100 brand name drugs in both Medicaid and Medicare Part D and the findings showed that Medicaid drug rebates required by law reduced expenditures by 45 percent, while Medicare Part D rebates secured by private drug plans reduced expenditures by only 19 percent.<sup>1</sup>

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<sup>1</sup> Department of Health and Human Services, Office of Inspector General, *Higher Rebates for Brand-Name Drugs Results in Lower Costs for Medicaid Compared to Medicare Part D*, August 2011.

***Medicare Drug Rebates Would Not Shift Costs to Seniors***

Research finds that Medicare beneficiaries would not be negatively affected if drug rebates were restored in the Medicare program. This is essential because half of the 50 million people who rely on Medicare for health care live on annual incomes of \$22,500 or less.<sup>2</sup> Additionally, Medicare beneficiaries already spend about 15 percent of their income on health care expenses—three times more than people with Medicare.<sup>3</sup>

***Medicare Drug Rebates Do Not Pose a Threat to Pharmaceutical Research and Development***

Several studies show that pharmaceutical spending on research and development is not at risk if rebates were restored.<sup>4</sup> Research and development investments in particular types of drugs are not directly linked to specific revenue sources, such as Medicaid. Furthermore, our own research on the seven largest U.S.-based pharmaceutical manufacturers found that these drug companies spend more than twice as much on marketing, advertising, and administration as they spend on R&D.<sup>5</sup> All of these findings clearly demonstrate that reinstating Medicare drug rebates will not limit research and development.

In order to preserve and protect Medicare without negatively affecting low- and middle-income beneficiaries, Congress should pass legislation restoring drug rebates in Medicare. Families USA urges all Senators to become a co-sponsor of S. 740, the *Medicare Drug Savings Act of 2013*. The Congressional Budget Office estimates that S. 740 would save \$141 billion over 10 years. Restoring drug rebates in Medicare represents a principled approach to controlling Medicare spending that is also supported by the vast majority of the American public.<sup>6</sup>

Thank you for the opportunity to submit a statement for the record.

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<sup>2</sup> Richard Frank and Jack Hoadley, Health Affairs Blog, *The Medicare Part D Drug Rebate Proposal: Rebutting An Unpersuasive Critique*, December 2012; Kaiser Family Foundation, *Policy Options to Sustain Medicare for the Future*, January 2013.

<sup>3</sup> Kaiser Family Foundation, *Policy Options to Sustain Medicare for the Future*, January 2013.

<sup>4</sup> Richard Frank, Kaiser Family Foundation, *Prescription Drug Procurement and the Federal Budget*, May 2012.

<sup>5</sup> Families USA, *No Bargain: Medicare Drug Plans Deliver High Prices*, January 2007.

<sup>6</sup> Kaiser Family Foundation, Robert Wood Johnson Foundation and the Harvard School of Public Health, *The Public's Health Care Agenda for the 113th Congress*, January 2013.

